



## **Environmental Defense Fund**

### **Comments on Proposed Significant New Use Rules on Certain Chemical Substances (21-3.5e)**

**Docket ID:** [EPA-HQ-OPPT-2021-0568](#) (June 24, 2022)

**Submitted:** July 25, 2022

#### **Introduction**

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) on the proposed significant new use rules (SNURs) addressing several chemical substances (batch 21-3.5e) under the Toxic Substances Control Act (TSCA).<sup>1</sup> Premanufacture notices (PMNs) on each of the chemical substances included in this proposed rulemaking were submitted to and reviewed by EPA, and all of the substances are subject to final TSCA section 5(e) orders.<sup>2</sup>

EDF's comments focus on a subset of 15 SNURs, specifically:

- The NCEL requirements as an alternative regulatory option for the significant new use (SNU) of absence of a respirator with a specified assigned protection factor (P-20-0112, P-20-0113, P-20-0114, P-20-0115, P-20-0116, P-20-0117, and P-21-0125);
- The lack of a SNU for a release to the environment for several persistent, bioaccumulative, and toxic chemical substances (P-21-0018, P-21-0023/P-21-0064, P-21-0027, and P-21-0042);
- The lack of a SNU for release to water greater than the concentration of concern (P-21-0017);
- The lack of a SNU that addresses risks to worker (P-18-0143); and
- The insufficient basis for the cut-off used in the SNU for consumer use for P-21-0013.

In addition, we identify the need to rectify chemical identity issues for several PMN substances.

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<sup>1</sup> EPA, Significant New Use Rules on Certain Chemical Substances (21–3.5e), 87 Fed. Reg. 37783, June 24, 2022, <https://www.govinfo.gov/content/pkg/FR-2022-06-24/pdf/2022-13360.pdf>

<sup>2</sup> If EPA determines that the information available to it about a chemical substance is insufficient to allow a reasoned evaluation of its health and environment effects; or that in the absence of sufficient information, the substance may present an unreasonable risk of injury to health or the environment; or that the substance enters or may enter the environment in substantial quantities or may cause significant or substantial human exposure, EPA may issue an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the substance. 15 U.S.C. § 2604(e) (“TSCA section 5(e)”).

**1. EDF supports the use of NCELS as a significant new use for P-20-0112, P-20-0113, P-20-0114, P-20-0115, P-20-0116, P-20-0117, and P-21-0125.**

EDF commends EPA for including NCEL requirements as an alternative regulatory option for the SNU of absence of a respirator with a specified assigned protection factor (APF) for SNURs P-20-0112, P-20-0113, P-20-0114, P-20-0115, P-20-0116, P-20-0117, and P-21-0125.

In the preamble of this batch of proposed SNURs, EPA states:

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure to workers, the underlying TSCA Order usually requires that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL), and includes requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. No comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELS as an alternative to the 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30.<sup>3</sup>

Other SNURs that include absence of a respirator as a SNU do not include the NCEL alternative. For example, P-19-0073 includes as a SNU absence of the use of a respirator with an APF of 1,000. Based on EPA's determination of the appropriate APF, the Agency could determine a NCEL. The order similarly requires the use of a respirator with an APF of 1,000. EPA would likely have determined that 1,000 was the appropriate APF by essentially generating a NCEL. Thus, while EPA did not include a NCEL in the order, it could easily include a NCEL in the SNUR.

At a minimum, EPA should explain when it will include NCELS as an alternative regulatory option to the SNU of absence of a respirator with a specified APF and when it will not.

**EPA should include failure to follow NCEL provisions as a significant new use.**

While EDF supports this approach as a first step, for the following reasons EDF encourages EPA to require that the NCEL approach be used in lieu of the absence of respirator with a specified APF SNU. After conducting a risk assessment specific to the information provided by a PMN submitter or in the absence of specific information using an assessment based on defaults, EPA will determine if the manufacturing, processing, distribution in commerce, use and disposal presents an unreasonable risk. When unreasonable risks are identified for workers, EPA will often specify workplace controls that can mitigate the unreasonable risk. This often involves the use of personal protective equipment, including respirators. Where a respirator would be required, EPA will identify the APF needed to mitigate the unreasonable risk. This APF is specific to the scenario(s) that EPA has evaluated. It will be dependent on the specific of the

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<sup>3</sup> EPA, Significant New Use Rules on Certain Chemical Substances (21–3.5e), 87 Fed. Reg. 37783, June 24, 2022, <https://www.govinfo.gov/content/pkg/FR-2022-06-24/pdf/2022-13360.pdf>

facilities and the processes at that facility, or in the absence of specifics in the new chemical submission, EPA will use default scenarios.

Thus, the use of a respirator with a specific APF should not be treated as an ongoing use as if the respirator were specific to a chemical. The APF of the respirator is not specific to the chemical. The appropriate respirator is the respirator both applicable to the type of chemical being used and the level of workplace exposure to the chemical. Since the level of workplace exposure will depend on the specifics of the workplace, EPA cannot predetermine whether the use of a respirator with a specific APF will lessen exposure sufficiently across different uses and different production and use scenarios so that the unreasonable risk is mitigated. This is the case even for scenarios similar to those in the PMN because EPA does not know what the baseline workplace exposure level will be for a particular facility.

Therefore, in issuing SNURs in which a SNU is used in the absence of a respirator with a specific APF, there could be ongoing uses (in which respirator with a specified APF is used) that present an unreasonable risk. This is not an unusual event. Indeed, it is something that is reasonably foreseen. A use in which properly wearing a respirator with the APF specified in the order with the PMN submitter and identified in the SNUR could result in an unreasonable risk even for the same use if the parameters of the use change, including changes in the quantity of the chemical produced or used, differences in the parameters of the process, or use of different or fewer engineering or administrative controls. This is why OSHA and NIOSH do not base workplace protection on the use of a respirator. Workplace protection is based on characterizing the workplace hazard and using hazard communication and the hierarchy of controls to mitigate the hazard. EPA should apply this paradigm to SNURs and not rely solely on PPE, clearly the least effective way of addressing unreasonable risks in the workplace.

## **2. The SNUR for P-18-0143 should include as a significant new use the absence of worker protection and hazard communication.**

In the preamble to the proposed SNUR for P-18-0143, EPA presents a range of adverse human health effects as well as toxicity to aquatic organisms:

Based on available data on an analogue, EPA has identified concerns for systemic effects and reproduction/developmental toxicity. Based on analogue data for the low molecular weight fraction and information in the Safety Data Sheet, EPA has also identified concerns for corrosion to all tissues and skin sensitization.<sup>4</sup>

While the requirements of the order and the proposed SNUs address potential risks to consumers and to aquatic organisms, they do not completely mitigate the unreasonable risk. Despite the range of adverse health effects associated with the substance and the risks to workers identified by EPA, EPA did not require worker protection in the order. In the order, EPA described the risks to workers as follows.

Risks to Workers: Based on the hazard determination and available quantitative and qualitative risk information, EPA identified risk for the New Chemical Substance. Risks

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<sup>4</sup> EPA, Significant New Use Rules on Certain Chemical Substances (21–3.5e), 87 Fed. Reg. 37783, June 24, 2022, <https://www.govinfo.gov/content/pkg/FR-2022-06-24/pdf/2022-13360.pdf>

were identified for workers for reproductive effects via inhalation based on quantitative hazard data for analogue (MOE 49; Benchmark MOE = 100; Fold Factor = 2.1). Risks were identified for workers for reproductive effects via dermal contact based on quantitative hazard data for analogue (MOE = 2; Benchmark MOE = 100). Corrosion to all tissues and skin sensitization hazards to workers via inhalation and dermal contact were identified based on analogue data for the L.MW fractions and information provided in the SDS. Risks for these endpoints were not quantified due to a lack of dose-response for these hazards. However, exposures can be mitigated by the use of appropriate PPE, including impervious gloves, eye protection, and respiratory protection. *EPA expects that employers will require, and that workers will use appropriate PPE consistent with the SDS prepared by the Company, in a manner adequate to protect them.* (emphasis added)<sup>5</sup>

Despite identified worker risks, the proposed SNUR for P-18-0143 does not include as a SNU the absence of worker protection and hazard communication, apparently because worker protection was not a requirement of the order given EPA's assumption at the time that, even in the absence of regulatory requirements, employers will require appropriate worker protection.

EPA announced in March 2021 that it changed its PMN review approach regarding worker protection, and no longer assumes that – in the absence of a regulatory requirement – employers will provide and require the use of protective equipment to mitigate risks to workers.<sup>6</sup> EDF commends EPA for this stated change but is concerned that this SNUR continues to rely on the earlier false premise about worker exposure that was used in the order. For purposes of SNURs, EPA should not rely on this premise in determining what is a SNU. EPA has not provided any information in the docket for these SNURs to support the assumptions in the Health Risk Assessment on the use of personal protective equipment.

**Given the identified risk to workers, EPA should modify its proposed SNUR for P-18-0065 to identify a NCEL and add the following significant new use:**

- ***Use in the absence of worker protection based on the identified NCEL and hazard communication***

Use of the substance without worker protection and hazard communication as compared to use with worker protection and hazard communication will “increase[] the magnitude and duration of exposure of human beings”<sup>7</sup> and thus should be considered a SNU. This SNU is particularly important given the range of adverse health effects associated with the substance and EPA's own

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<sup>5</sup> EPA, TSCA Section 5 Order For A New Chemical Substance: Premanufacture Notice Number (PMN) Number: P-18-0143, signed by EPA September 16, 2020, <https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0568-0003>

<sup>6</sup> EPA, Important Updates on EPA's TSCA New Chemicals Program, published March 29, 2021, updated May 24, 2022, <https://www.epa.gov/chemicals-under-tsca/important-updates-epas-tsca-new-chemicals-program>

<sup>7</sup> 15 U.S.C § 2604(a)(2)(C) (“TSCA section 5(a)(2)(C)”)

assessment identifying risks to workers, who are specifically identified in TSCA section 3 as a “potentially exposed or susceptible subpopulation.”<sup>8</sup>

According to EPA’s public Notice of Commencement (NOC) data, manufacture of substance P-18-0143 has not been commenced. Thus, there are currently no ongoing uses of this chemical substance.

**3. The SNURs for P-21-0018, P-21-0023/P-21-0064, P-21-0027, and P-21-0042 should include as a significant new use any use that results in release to the environment.**

EPA has proposed four SNURs on five chemical substances used in photolithography that the Agency states may be persistent, bioaccumulative, and toxic chemical substances. EPA estimated that the chemical substances will persist in the environment for more than 2 months and have a bioaccumulation factor of greater than or equal to 1,000. Additionally, EPA has identified concerns for a variety of adverse effects, including liver toxicity, neurotoxicity and reproductive (developmental) toxicity. EPA also states that it was unable to estimate the environmental hazard of the chemical substances.

EPA’s final policy statement *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (PBT Policy)<sup>9</sup> reflects the Agency’s recognition that PBT chemical substances present a heightened risk to the environment and human health. Because PBT chemical substances build up in the environment, animals, and humans, *any degree of change in the use or release of PBT chemical substances could increase the magnitude and duration of exposure*, and potentially lead to widespread health effects in the long-term.

**Given their persistent and bioaccumulative properties and demonstrated toxicity, EPA should modify its proposed SNURs for P-21-0018, P-21-0023/P-21-0064, P-21-0027, and P-21-0042 to add the following significant new use:**

- *Use that results in release to the environment (air, water, and land)*

In the orders for these chemical substances, EPA states that risks to the general population were not reported in the order “because risks were not quantified due to insufficient information on hazard.” In addition, EPA states that “[a]cute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are unknown due to insufficient information.”

This raises the question of why EPA did not determine that “the information available to the Administrator is insufficient to permit a reasoned evaluation”<sup>10</sup> and require the information needed to quantify the risks prior to commercialization. Even though EPA chose not to make that finding during its PMN review, the range of adverse effects that EPA identified concerns for and the lack of information to quantify risks to the general population and aquatic organisms should

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<sup>8</sup> 15 U.S.C § 2602(12)

<sup>9</sup> EPA, *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*, Policy Statement, November 4, 1999, <https://www.govinfo.gov/content/pkg/FR-1999-11-04/pdf/99-28888.pdf>

<sup>10</sup> 15 U.S.C. § 2604(a)(3)(B) (“TSCA section 5(a)(3)(B)”)

have at least led EPA to prohibit release to the environment of the substances. This limitation on environmental releases should then have been mirrored in the SNUR by designating any release of these substances to the environment as a SNU. Further, taking these actions would be consistent with the Agency's own PBT Policy. Neither in the order nor in the SNUR does EPA indicate what information would support an approach that is inconsistent with its PBT Policy.

According to EPA's public Notice of Commencement (NOC) data,<sup>11</sup> manufacture of substance P-21-0023/P-21-0064, P-21-0027, and P-21-0042 has not been commenced. Thus, there are currently no ongoing uses of these chemical substances.

**4. The SNUR for P-21-0017 should include as a significant new use any use that results in release to water greater than the concentration of concern.**

EPA determined that P-21-0017 presents moderate environmental hazard and estimated a chronic concentration of concern (COC) for toxicity to aquatic species equal to 590 parts per billion (ppb). However, despite the potential for aquatic risk at this COC, EPA did not restrict water releases to protect aquatic species from such risk in the order for this PMN.

In the Ecotoxicity Report for P-21-0017, EPA found no risk to aquatic species because estimated surface water releases and concentrations were below the COC. However, without restrictions on water releases, these surface water concentrations will likely increase, which could very well lead to surface water concentration above the COC, ultimately leading to environmental risk.

Accordingly, EPA should have restricted water releases to levels equal to or below the estimated COC in the order for this PMN to ensure that aquatic life is protected against unreasonable risk. Despite not taking this protective action in the order, EPA can and should designate water releases that result in surface water concentrations higher than the COC (590 ppb) as a SNU in the proposed SNUR for P-21-0017. This SNU is needed to ensure that EPA has an opportunity to review and determine if the use presents an unreasonable risk, as required under TSCA. It would also reduce potential human exposure levels via water-based exposure pathways as well.

According to EPA's public Notice of Commencement (NOC) data, manufacture of substance P-21-0017 has not been commenced. Thus, there are currently no ongoing uses of the chemical substance, including no ongoing water releases.

**5. EPA should provide a basis for its 1% cut-off in the significant new use of P-21-0013 in consumer products.**

In the Health Risk Assessment for P-21-0013, EPA states:

For the new chemical substance, EPA identified hazards including skin sensitization and irritation to the eyes and respiratory tract. Submitted tests of the new chemical substance reported the test substance to have weak skin sensitization potential (negative for non-

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<sup>11</sup> EPA's public Notice of Commencement (NOC) data includes two data sources: the Federal Register ("Certain New Chemicals; Receipt and Status Information" notices) and EPA's web-table ("Notices of Commencement Received under TSCA," <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/notices-commencement-received-under>)

guideline human repeat insult patch test at 10%; positive in OECD 429 mouse LLNA assay with an EC3 value of 42%) and to show negative results for skin irritation (non-guideline closed patch test in humans) and genotoxicity in vitro (OECD 487 micronuclei assay in human lymphocytes and OECD 471 bacterial reverse mutation assay). EPA did not identify a suitable POD based on no significant quantitative hazards identified for quantitative risk assessment. EPA qualitatively evaluated irritation and sensitization effects.

and

EPA assumes that skin sensitization is possible from exposure to a new chemical substance in consumer products because the new chemical substance is intended to be used in the consumer products at concentration levels  $\geq 1\%$  and therefore its sensitizing properties are assumed to persist even in the presence of other unknown components. (Citing Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Eighth Revised Edition (UN, New York, <https://doi.org/10.18356/f8fbb7cb-en>; Chapter 3.4).

Yet, the SNU for consumer use is set at 1%. EPA did not identify a suitable point of departure (POD) but is establishing a level with the only basis apparently the GHS guidance that persistence of effects occurs at concentration levels greater than or equal to 1%. This is particularly problematic given that EPA identified skin sensitization. Once sensitized, even low levels of exposure will result in a reaction. EPA includes no buffer but would not require a SNUN for uses up to 1%. Because EPA is making assumptions in lieu of a quantitative risk assessment, the Agency at a minimum should include an uncertainty factor in setting the level for the SNU. Further, in setting the level for the SNU, EPA does not consider that consumers may use multiple products that contain the chemical substance. This is reasonably foreseen because the intended uses include as a fragrance in shampoos and body washes, deodorants and cosmetics, laundry detergents and other household products, including solid air freshener. Consumers often have preferences for certain fragrances and may buy and use more than one product with the same fragrance.

For the reasons discussed above, EPA should provide a more substantive risk basis for its choice of 1% as the SNU cut-off.

According to EPA's public Notice of Commencement (NOC) data, manufacture of substance P-21-0013 has not been commenced. Thus, there are currently no ongoing uses of this chemical substance.

#### **6. EPA should address various issues related to chemical identity confidentiality business information claims for several PMNs in this batch of proposed SNURs.**

In addition to the recommended SNUs discussed above, we recommend that EPA address various issues related to chemical identity confidential business information (CBI) claims apparent in the proposed SNURs for this batch of PMNs.

**A. EPA must review the chemical identity confidentiality claims for P-20-0005, P-20-0113, P-21-0018, and P-21-0063, as TSCA section 14 requires.**

All but five of the PMNs subject to the proposed SNURs have generic chemical identities. Of the PMNs with generic chemical identities that have commenced production, EPA did not review and approve the CBI claims on chemical identity, nor assign a unique identifier (UID), for three PMNs: P-20-0005, P-20-0113, and P-21-0063. Additionally, while EPA did review and approve the chemical identity CBI claim for P-21-0018, the Agency did not assign the PMN a UID, making it difficult to tie new and existing chemical documents to this specific chemical substance.

For new chemicals coming to market, chemical identity CBI claims in PMNs must be reasserted and substantiated when a Notice of Commencement (NOC) is filed indicating that commercial distribution of a chemical has begun.<sup>12</sup> EPA is required to review and approve chemical identity CBI claims within 90 days of receipt of a claim.<sup>13</sup> EPA is also responsible for assigning a “unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure.”<sup>14</sup>

EDF is concerned that EPA appears not to have completed its review of the chemical identity CBI claims for three PMNs (P-20-0005, P-20-0113, and P-21-0063) as required by TSCA section 14(g)(1)(A) and EPA’s regulations at 40 CFR 720.85. Furthermore, we are concerned that EPA has not yet assigned P-21-0018 a UID, as required by TSCA section 14(g)(4). The CBI issues raised here should be addressed immediately.

**B. EPA should ensure the SNURs for P-19-0098, P-20-0058, and P-21-0063 reflect the most up to date identities for these chemical substances.**

As written, the proposed SNURs for P-19-0098, P-20-0058, and P-21-0063 do not reflect these chemical substances’ most up to date chemical identities.

Specifically, in the proposed SNURs, EPA refers to P-19-0098 and P-20-0058 by their generic name, despite the fact that the specific name for both PMNs is provided in EPA’s public NOC data. Regarding P-19-0098, the submitter withdrew its CBI claim when it amended its original NOC on October 25, 2021. The specific name for P-19-0098 is “(S) Phosphoric acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol and 1,2-ethanediol” and its CAS number is 2248116-55-2. The specific name and CAS number should be reflected in the final SNUR for P-19-0098.

Regarding P-20-0058, only the specific name of the chemical is provided via EPA’s NOC data. The specific name for P-20-0058 is “(S) Maltodextrin, polymer with 2-propenoic acid and n,n,n-trimethyl-2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethanaminium chloride (1:1), sodium salt, peroxydisulfuric acid ([HO]S(O)2]2O2) sodium salt (1:2)-initiated,” though its CAS number is

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<sup>12</sup> 40 CFR 720.85(b)(1)

<sup>13</sup> 15 U.S.C. § 2613(g)(1)(A) (“TSCA section 14(g)(1)(A)”)

<sup>14</sup> 15 U.S.C. § 2613(g)(4) (“TSCA section 14(g)(4)”)

unavailable through EPA’s NOC data and does not appear on EPA’s non-CBI TSCA Inventory as of March 2022. The specific name and CAS number should be reflected in the final SNUR for P-20-0058.

Finally, the proposed SNUR for P-21-0063 reflects an outdated generic name. In May 2022, the submitter of this PMN updated the generic name of this chemical substance when it amended its original NOC on May 11, 2022. According to EPA’s NOC data, the most up to date generic name for this chemical substance is “(G) Pyrazole-polycarboxylic acid, polyhaloaryl-polyhydro-alkyl-polyalkyl ester.” EPA should ensure that the most up to date generic name is reflected in the final SNUR for P-21-0063.

### **Conclusion**

EPA should strengthen the 15 SNURs discussed in these comments. The significant new uses EDF recommends are consistent with the TSCA section 5(a)(2)<sup>15</sup> factors EPA should consider in determining whether a use of chemical substance is a significant new use. These significant new uses are also consistent with the hierarchy of controls, EPA’s PBT Policy and would protect frontline communities, consumers, and workers, helping to fulfill the Biden Administration’s commitment to promote worker rights and advance environmental justice. EDF also recommends that EPA address the various issues related to chemical identity confidentiality claims identified in these comments.

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The Environmental Defense Fund appreciates EPA’s consideration of these comments.

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<sup>15</sup> 15 U.S.C § 2604(a)(2)