Environmental Defense Fund Comments on
Significant New Use Rules on Certain Chemical Substances
Docket ID: EPA-HQ-OPPT-2019-0226[1]

Submitted August 7, 2019

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on EPA's proposed rules covering 3 significant new use rules (SNURs) addressing 3 chemical substances, *see* 84 Fed. Reg. 32,366 (Jul. 8, 2019), under the Toxic Substances Control Act (TSCA). Premanufacture notices (PMNs) on each of the chemical substances were submitted to and reviewed by EPA. EPA has issued final determinations for all of the PMN substances (determining that each of them is "not likely to present an unreasonable risk"): P-16-0417, P-18-0239, and P-18-0240. None of the PMN substances is subject to a final TSCA § 5(e) consent order.

EDF supports EPA's promulgation of SNURs for all of the chemical substances, but identifies a number of flaws in EPA's approach.

EDF is particularly concerned about EPA's unfounded decision not to include in the SNUR for P-16-0417 any workplace protections and to allow manufacture of the PMN substance without notification even when it contains levels of isocyanate residuals that are so high that they appear to be without precedent in EPA's review of new chemicals under TSCA. See section I of these comments.

Contents:

[1] The docket is at https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2019-0226.

I. EPA must significantly strengthen the proposed SNUR for P-16-0417 to fully address the risks posed by residual isocyanates.

In its proposed SNUR for P-16-0417, EPA has proposed that manufacture of the PMN substance would not constitute a significant new use requiring prior notification to EPA unless isocyanate residuals exceed 7% or polymeric isocyanate residuals exceed 13%. 84 Fed. Reg. at 32,371 (to be codified at 40 C.F.R. § 721.11295(a)(2)(i)). The proposed SNUR sets the allowable residual isocyanate levels drastically higher than it has for similar new chemicals, where limits are set at 0.1% or 0.2%. EPA has failed to provide any basis or rationale for its proposed residual levels in any of the documents it has made publicly available, nor has it demonstrated how they would be protective of worker health. Nor has EPA proposed any other workplace protections that would limit occupational inhalation exposures, and has not even included in the SNUR the respirator with an APF of 50 it assumed would be used as the basis for its determination that the PMN substance is not likely to present an unreasonable risk under its intended conditions of use. EPA has also failed to address the elevated risk associated with industrial use of the PMN substance in spray applications; it neither identifies such use as a significant new use, nor specifies the need to use the type of respirator that it has always previously specified – one with an APF of 1,000 – as needed to be sufficiently protective if the chemical is spray-applied. As discussed below, EPA must address these issues in its final SNUR.

EPA has consistently recognized that isocyanates pose significant risks to workers. For example, in its Consent Order for P-17-0024 and P-17-0025, EPA stated:

> Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent ***. Once a worker is sensitized to diisocyanates, subsequent exposures can trigger severe asthma attacks. Spray application and heated processes are associated with higher incidences of asthma than other application methods because they can generate airborne isocyanate vapors and mists, which lead to worker exposure via the respiratory and dermal routes. Most workers who develop diisocyanate asthma have experienced long periods of exposure (months or longer); however, the minimum exposure to isocyanates that can elicit sensitization responses or asthma is unknown. In addition, immune response and subsequent disease in humans can vary significantly between individuals ***. Fatalities linked to diisocyanate exposures in sensitized persons have been reported ***.[2]

In this case, "EPA identified pulmonary effects, irritation to all tissues, and dermal and respiratory sensitization based on compound reactivity of the isocyanate groups." TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-16-0417 at p. 4, https://www.epa.gov/sites/production/files/2019-07/documents/p-16-0417_determination_non-cbi_final.pdf; *see also* 84 Fed. Reg. at 32,368 (the preamble in the proposed rule does not specify pulmonary effects even though EPA has identified it as a risk in the "not likely" determination). In its "not likely" determination for this substance, EPA also stated: "Risks were identified for workers for pulmonary effects via inhalation exposure based on quantitative data for a component of the new chemical substance (MOE = 0.7; Benchmark MOE = 30; Inhalation fold factor = 46). Irritation and sensitization effects hazards to workers via inhalation and dermal contact were identified based on reactivity and residual isocyanates." *Id.* at 6. EPA concluded that such risks "can be mitigated" through assumed reliance on the use of certain PPE.[3]

Despite these identified risks, the residual isocyanate triggers proposed in this SNUR greatly exceed analogous limits EPA has set in prior similar cases, and were proposed with absolutely no

[2] Consent Order for P-17-0024 and P-17-0025 at p. vii, https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_17_0024c.pdf.

[3] EDF strongly opposes on legal, scientific and policy grounds EPA's reliance on expected use of PPE as a basis for making "not likely" determinations on new chemicals or otherwise failing to address risks to workers posed by chemicals being reviewed under TSCA. See these detailed EDF Health blog posts: http://blogs.edf.org/health/2019/02/21/the-trump-epa-is-throwing-workers-facing-risks-from-new-tsca-chemicals-under-the-bus/; and http://blogs.edf.org/health/tag/myth-busting/.

explanation. The proposed SNUR states a company must file a significant new use notice with EPA if it plans to:

> "manufacture (including import) the substance with isocyanate residuals greater than 7% and polymeric isocyanate residuals greater than 13%."

84 Fed. Reg. at 32,371 (to be codified at 40 C.F.R. § 721.11295(a)(2)(i)). These levels of residual isocyanates do not appear to be even remotely protective of worker health because EPA has identified for similar chemicals dermal and respiratory sensitization as endpoints of concern *unless* the "concentration of free residual isocyanates is greater than 0.1% by weight."[4]

Additionally, these levels of residual isocyanate are dramatically higher than the majority of the proposed SNURs EPA has published. Over the past year, EPA's proposed SNURs have generally set the residual isocyanate trigger at either 0.1% or 0.2% residual isocyanate by weight. See, e.g., 84 Fed. Reg. 37,199 (Jul. 31, 2019) (to be codified at 40 C.F.R. § 721.11279(a)(2)(i)); 84 Fed. Reg. 9,999 (Mar. 19, 2019) (to be codified at 40 C.F.R. § 721.11237(a)(2)(iii)); 83 Fed. Reg. 57,634 (Nov. 15, 2018) (to be codified at 40 C.F.R. § 721.11206(a)(2)(iii)); 83 Fed. Reg. 47,004 (Sept. 17, 2018) (to be codified at 40 C.F.R. § 721.11125(a)(2)(i)).

The documents EPA developed in the course of its review of this PMN, the PMN and associated attachments, the proposed SNUR, and the "not likely" determination for this chemical substance all fail to acknowledge, let alone explain, how these far higher residual isocyanate levels were selected, or whether and if so how they adequately address the identified risks posed by the isocyanate groups. Where an agency changes its policy and practice, the agency must acknowledge that change and provide a well-reasoned and complete explanation for its action. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy *sub silentio*."); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-44 (1983). EPA must do so here if it decides to depart from its practice of setting residual isocyanate levels at either 0.1% or 0.2%.

EPA's proposed SNUR also fails to include *any* workplace notification requirements for this SNUR, as discussed in section 4.D. of these comments. Due to the residual isocyanates in this chemical substance, the lack of *any* workplace triggers is particularly concerning. EPA has not even proposed any broad notification triggers related to inhalation exposures. For instance, in addition to requiring notification absent use of the PPE that EPA assumes is being used, EPA must include a provision that would require notification if inhalation exposures are occurring. Past SNURs include the following triggers:

[4] Consent Order for P-16-0307 at p. vi, https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_16_0307.pdf.

- It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure to workers; or
- It is a significant new use to manufacture or use the substance with methods that generate a dust, spray, mist, or aerosol.

In this case, EPA needs to set as a trigger any new use that would generate a dust, spray, mist, or aerosol.

Lastly, neither the proposed SNUR nor the "not likely" determination address the elevated risk to workers when the chemical substance is spray-applied. As mentioned previously, EPA has not proposed any workplace limitations; therefore, considering the broad condition of use, it is reasonable to expect that the chemical substance could be spray-applied. This use is particularly concerning considering NIOSH's Alert for isocyanate use in the automotive industry, which states that due to the high risk to workers:

> [w]hen workers are spraying [isocyanates] or are inside the spray enclosure during spraying, make sure they use full-facepiece, supplied-air respirators operated in a pressure-demand or other positive-pressure mode.[5]

OSHA guidance makes clear that the respirator NIOSH is describing as a "full-facepiece, supplied-air respirator" is a respirator with an APF of 1,000.[6] NIOSH also indicates more generally that a full-facepiece respirator is needed to protect workers from isocyanates even in exposure settings not involving spray application. OSHA guidance makes clear that such a respirator is one with an APF of 50.[7]

These APF levels are consistent with past SNURs EPA has developed for PMN substances containing isocyanates, where EPA has specified that:

> respirators must provide a National Institute for Occupational Safety and Health with assigned protection factor (APF) of at least 50 or an *APF of at least 1,000 if spray applied*.

[5] NIOSH, *Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications* at p. 5 (Sept. 2006), https://www.cdc.gov/niosh/docs/2006-149/pdfs/2006-149.pdf?id=10.26616/NIOSHPUB2006149.
[6] OSHA, *Assigned Protection Factors for the Revised Respiratory Protection Standard* at p. 6 (2009), https://www.osha.gov/Publications/3352-APF-respirators.pdf.
[7] OSHA, *Assigned Protection Factors for the Revised Respiratory Protection Standard* at p. 5 (2009), https://www.osha.gov/Publications/3352-APF-respirators.pdf.

83 Fed. Reg. 57,634, 57,653 (to be codified at 40 C.F.R. § 721.11211(a)(2)(i)) (emphasis added). Despite NIOSH and OSHA guidance and past EPA practice, EPA has entirely failed to address the risks posed by this chemical substance, including if it is spray-applied, and it must do so in its final rule and provide a rationale for any deviations from past practice.

Therefore, EPA must modify the SNUR to require notification whenever there is potential for workplace inhalation exposures, or at a minimum specify that a respirator with an APF of at least 50 must be provided and used, or where the chemical is spray-applied, an APF of 1,000.

II. EPA's failure to issue section 5 orders for these chemical substances is unlawful.

EDF has previously commented on the illegality of EPA's SNUR-only approach, now "adopted" by the New Chemicals Review Program. *See* EDF Comment on New Chemicals Decision-Making Framework, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071; EDF Comments on Significant New Use Rules on Certain Chemical Substances, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0575-0082. EDF incorporates by reference and reiterates those comments here.

In sum, TSCA does not allow EPA to rely on non-5(e) order SNURs in order to make a "not likely to present an unreasonable risk" finding for a PMN substance. EPA can only make a section 5(a)(3)(C) "not likely to present an unreasonable risk" finding for a new "chemical substance" based on the substance *as a whole* and under its "conditions of use," which includes intended, known, or reasonably foreseen conditions of use. 15 U.S.C. § 2604(a)(3)(C). Section 5(g) also requires EPA to make a public statement articulating any finding – which must be made "in accordance with subsection (a)(3)(C)" – that "*a chemical substance* *** is not likely to present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(g). EPA has never articulated how this approach is consistent with TSCA, or why this SNUR-only approach is sufficiently health protective.

EPA has never responded to EDF's (or any others') comments it received on its framework. In response to the filing of a legal challenge, EPA asserted it was not using its framework. EPA did respond to EDF's comments cited above on an earlier batch of proposed non-5(e) SNURs in the preamble to its rule finalizing those SNURs.[8] However, EPA's response simply referred to its response to that legal challenge.

Yet EPA has never issued any update to that framework, nor a different framework, leaving the basis for its new chemicals decisions opaque and largely unexplained. Moreover, with the

[8] Those final SNURs are available at 84 Fed. Reg. 13531 (Apr. 5, 2019). EDF's comments on those SNURs as proposed are available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0575-0082.

proposal of these "non-order SNURs," as well as its finalization of the earlier batch of such SNURs, despite its assertion to the contrary, EPA appears now to be deploying its earlier framework in reviewing at least some PMNs. Of the PMNs subject to the current batch of proposed SNURs, EPA has issued "not likely to present an unreasonable risk" determinations for all of them.

While this approach is illegal, EDF nevertheless supports promulgation of the SNURs at this time because otherwise there will be no limitations in place for these chemical substances.

III. EPA should generally designate as a significant new use any use of a chemical substance other than the uses EPA evaluated in its PMN review and determined are not likely to present an unreasonable risk.

One of EPA's proposed SNURs does not include designation of *any* use other than the PMN use as requiring notification; it does not refer to or even mention either the generic or the specific use of the PMN substance. This is especially concerning because EPA identified a number of health concerns for this chemical:

- P-16-0417: Pulmonary effects, irritation to all tissues, and dermal and respiratory sensitization

It is clear from the TSCA section 5(a)(3) determination documents for this PMN chemical that EPA has failed to assess any *uses* other than the specific uses identified by the PMN submitter. Hence, barring such a broader assessment and associated determination, EPA needs to require notification for any use other than the specific use identified in the PMN.

It should be noted that for this chemical, EPA has included in the SNUR other types of triggers for notification: non-industrial use or use in a consumer product, *see* 84 Fed. Reg. at 32,371 (to be codified at 40 C.F.R. § 721.11295(a)(2)(i)). Although EDF supports inclusion of these notification triggers, EPA must also require notification for any *specific* use of the chemical for which EPA has not conducted an assessment of the risks posed by such use.

In its response to our similar comments on an earlier batch of non-5(e) SNURs, EPA asserted that our:

> suggested approach is overly broad. *** Based upon EPA's review of the relevant PMNs, the Agency identified uses that are appropriate for designation as ''significant new uses'' in order to ensure that EPA has an opportunity to review those uses in a SNUN submission at a later date and address any unreasonable risks at that time. TSCA § 5(a)(2) does not require EPA to take the catch-all

> approach advocated by commenters, and EPA believes a more tailored approach is warranted to avoid unduly burdensome regulations.[9]

This response entirely misses the point. Even if EPA's approach of bifurcating its consideration of intended vs. reasonably foreseen uses of a new chemical – by relegating the latter to a subsequent, separate review divorced from its review of the former – was not illegal, it creates serious potential for a "risk gap" to arise. That is, if EPA fails to require notification for any condition of use of the chemical that EPA did not include in its initial PMN review, and instead requires notification only for a subset of such conditions of use, then those additional conditions of use that do not trigger notification will never be assessed. EPA did not evaluate them in its initial review, and it will also not evaluate them in the future because the SNUR EPA has promulgated does not identify such conditions of use as a trigger requiring notification. Any such "gap" conditions of use can proceed unconditionally and any risks they pose will go unaddressed.[10] EPA's decision to deviate from the law's requirements by limiting the scope of its "not likely" determination to a new chemical's intended conditions of use is bad enough. It is even worse for EPA to compound that problem by not requiring notification of a company's intent to engage in conditions of use that extend beyond that scope.

IV. Where EPA finds risks to workers, EPA must regulate to ameliorate that risk.

Of the three PMNs covered by the proposed SNURs (for all of which EPA has made final "not likely" determinations), EPA found risks to workers for all of them.

The three PMN numbers are listed below along with the identified worker risks:[11]

- P-16-0417: pulmonary effects via inhalation exposure; irritation and sensitization via inhalation and dermal exposures*
- P-18-0239: developmental toxicity via dermal exposure; irritation via inhalation and dermal exposures*
- P-18-0240: developmental toxicity via dermal exposure; irritation via inhalation and dermal exposures*

[9] 84 Fed. Reg. 13531, 13534 (April 5, 2019).

[10] Notably, EPA does not refer to the uses other than the intended uses specified in the PMN as reasonably foreseen uses. This effort by EPA to narrow what it will consider "reasonably foreseen" is contrary to Congressional intent and established law. It is well established under the law that "[a] natural and probable consequence is a foreseeable consequence. But to be reasonably foreseeable [t]he consequence need not have been a strong probability; a possible consequence which might reasonably have been contemplated is enough." *People v. Medina*, 46 Cal. 4th 913, 920 (Cal. 2009) (internal citations and quotation marks omitted).

[11] For the endpoints with an asterisk, EPA did not quantify and/or stated that it could not quantify the magnitude of the risk due to lack of dose-response information.

In the "not likely" determination documents for all three of these cases, often despite the absence of data that would have allowed EPA to quantify some or all of the risks, EPA simply asserts that use of personal protective equipment (PPE) specified in the Safety Data Sheets (SDSs) prepared by the submitters will mitigate any risk, because "EPA expects that employers will require and workers will use appropriate PPE *** in a manner adequate to protect them."

EDF has discussed at length elsewhere[12] the many flaws in EPA's assertions about the adequacy of its reliance on SDSs and PPE. In the present context, however, we sought to examine the SNURs and SDSs for these PMN substances for three reasons:

- First, to determine whether the SDSs in fact specify the PPE that EPA had identified as needed and expected to be used in its "not likely" determinations for those same PMN substances.
- Second, to determine if the proposed SNURs incorporate the SDSs' protective measures.
- Third, to determine if the proposed SNURs incorporate EPA's specifications of the PPE it expects to be used.

These are important questions because, beyond the fact that SDSs impose no actual mandatory duties on PMN submitters or their workers to follow the protective measures the SDSs may recommend, those SDSs certainly impose absolutely no obligations on *other companies* that the SNUR would potentially apply to – that is, those entities who might engage in activities involving the PMN substance that could trigger a notification requirement to EPA if the SNUR is written appropriately. So it is critical to ask whether the SDS and SNUR actually incorporate (the latter as notification triggers) the workplace protections such as use of PPE on which EPA relied in determining that the PMN substance is not likely to present an unreasonable risk. If the SNURs do not, then companies would be free to make or use the PMN substance in the absence of the protective measures EPA assumes will be employed and without any obligation even to notify EPA they are doing so.

A. The PPE identified in the Safety Data Sheet must be as protective and specific as the PPE EPA relied on in making its "not likely" determination.

For one of the substances (P-16-0417), the "not likely" determination states that:

[12] *See* EDF blog posts: http://blogs.edf.org/health/2019/02/21/the-trump-epa-is-throwing-workers-facing-risks-from-new-tsca-chemicals-under-the-bus/; http://blogs.edf.org/health/tag/myth-busting/. EDF incorporates these comments by reference.

> exposures can be mitigated by the use of appropriate personal protective equipment (PPE), including impervious gloves, eye protection, and respiratory protection with an Assigned Protection Factor (APF) of at least 50. (p. 6)

Yet the SDS states:

> Use NIOSH approved respirator if there is potential to exceed exposure limit(s). A positive pressure, supplied-air respirator or a self-contained breathing apparatus is recommended when: airborne concentrations of isocyanate are known to exceed 0.005 ppm; operations are performed in a confined space or area with limited ventilation; material is heated or sprayed. Do not inhale vapors and fumes. Observe OSHA regulations for respirator use.[13]

Nowhere does the SDS specify use of a respirator with an APF of 50. The SDS is clearly not consistent with EPA's own description of it. Moreover, EPA has already identified a clear risk to workers from inhalation exposure to this chemical substance and determined that the means to ameliorate that risk is by wearing a respirator with an APF of 50.[14] To the extent the SDS can indicate that wearing a respirator with an APF of 50 is mandatory, it must do so to be consistent with the "not likely" determination.[15]

[13] Safety Data Sheet for P-16-0417, https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2019-0226-0012&attachmentNumber=6&contentType=pdf.

[14] *See* TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-16-0417, https://www.epa.gov/sites/production/files/2019-07/documents/p-16-0417_determination_non-cbi_final.pdf.

[15] EDF has previously explained why the PPE provisions in SDSs are not mandatory. *See* http://blogs.edf.org/health/2019/02/21/the-trump-epa-is-throwing-workers-facing-risks-from-new-tsca-chemicals-under-the-bus/; http://blogs.edf.org/health/tag/myth-busting/.

B. Some of the proposed SNURs fail to incorporate the corresponding SDSs' more specific recommended personal protective equipment.

In some instances, the recommendations of PPE in the SDSs are more specific than the PPE that EPA states it "expects" will be used and that it relies on as a basis for its "not likely" determinations. This is the case for the following PMNs covered by this batch of proposed SNURs:

- P-18-0239: SDS specifies use of a respirator with an APF of 10
- P-18-0240: SDS specifies use of a respirator with an APF of 10

Given EPA's reliance on the PPE recommended in the SDSs as a basis for its "not likely" determination, EPA must ensure that the PPE specified in the final SNURs matches the more specific aspects of the descriptions of PPE recommended in the SDSs.

C. The proposed SNURs fail to incorporate EPA's specifications of the PPE it expects to be used as a basis for its "not likely" determination.

The following quoted excerpts are all taken directly from the corresponding "not likely to present unreasonable risk" determination document for the PMN substance.[16]

- **P-16-0417**: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves, eye protection and respiratory protection with an Assigned Protection Factor (APF) of at least 50."
- **P-18-0239** and **P-18-0240**: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves, eye protection, and respiratory protection."

In contrast, the proposed SNURs associated with each of these PMNs lack any such provisions. For most of the PMNs, the only activities EPA proposes to designate as a significant new use are new *uses* of the chemical. In one instance, EPA proposes to designate as a significant new use manufacturing of the chemical substance with greater than the specified percentage of isocyanate residuals, but this SNU does not encompass the very specific PPE EPA relies on in its not likely determinations.

At a minimum, each SNUR needs to identify as a SNU the manufacturing, processing or use of the substance without use of the PPE EPA has stated it "expects" to be used as a basis for its "not likely" determination (as well as the additional specification of the APF in the SDSs discussed in sec. B). This would be best accomplished by incorporating these significant new uses into a distinct "protection in the workplace" section added to each SNUR, as we call on EPA to do in

[16] These determination documents are available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely.

subsection D below. In past SNURs, EPA has taken this approach, incorporating cross-references to the PPE provisions in EPA's generic SNUR regulations at 40 C.F.R. § 721.63. EPA should do so for these SNURs.

D. EPA should add provisions addressing "protection in the workplace" and "hazard communication" to the SNURs for the three PMNs, for all of which EPA found evidence of potential worker risks.

In the past, where EPA had raised concerns about worker risks, its SNURs included entire sections addressing "Protection in the workplace" and "Hazard Communication," and explicitly invoked and incorporated its associated SNUR regulations at 40 CFR § 721.63 and § 721.72.[17] See, for example, the SNURs codified at 40 CFR § 721.10095 or § 721.11000. None of the proposed SNURs for the three PMNs in this batch, for all of which evidence of worker risks is present (identified above at the beginning of this section), has any such provisions. EPA should add provisions to the SNURs identifying use without these relevant workplace protections as significant new uses.

We fail to understand why and how EPA concluded that no specific workplace exposure control requirements should apply to any of these substances. It is not clear from the proposed SNURs or other documents on these chemicals available in the docket why EPA has not included specific workplace exposure provisions in the proposed SNURs. EPA needs to explain the basis for these decisions.

E. The proposed SNURs fail to invoke and incorporate the Industrial Hygiene Hierarchy of Controls.

None of the proposed SNURs for the three PMNs in this batch, for all of which evidence of worker risks is present (identified above at the beginning of this section), has any provision calling for use of the Industrial Hygiene Hierarchy of Controls (HOC) for addressing workplace exposures to chemicals. The HOC is a basic tenet of industrial hygiene,[18] as well as a longstanding foundational element of the Occupational Safety and Health Administration's (OSHA) workplace safety policy[19] and of the National Institute for Occupational Safety and Health's (NIOSH) workplace safety guidance.[20] It gives strong preference to the use of

---

[17] *See* https://www.law.cornell.edu/cfr/text/40/721.63; https://www.law.cornell.edu/cfr/text/40/721.72.
[18] *See* Occupational Safety & Health Admin., *Informational Booklet on Industrial Hygiene* (1998), https://www.osha.gov/Publications/OSHA3143/OSHA3143.htm#How do.
[19] *See* CHEMICAL HAZARDS AND TOXIC SUBSTANCES, CONTROLLING EXPOSURES, https://www.osha.gov/SLTC/hazardoustoxicsubstances/control.html (last visited Sept. 14, 2018).
[20] *See* WORKPLACE SAFETY AND HEALTH TOPICS, HIERARCHY OF CONTROLS, https://www.cdc.gov/niosh/topics/hierarchy/ (last visited Sept. 14, 2018).

engineering or administrative control measures to eliminate or reduce the presence of potential hazardous substances in the workplace over EPA's reflexive resorting to the use of PPE, which represents the lowest tier (i.e., least preferred approaches) in the HOC.

We note that, in 2016, EPA proposed updates to its SNUR regulations "to align these regulations with revisions to the Occupational Safety and Health Administration's (OSHA) Hazard Communications Standard (HCS)." 81 Fed. Reg. 49598 (Jul. 28, 2016). EDF filed comments supporting the changes, most notably EPA's proposal to incorporate the HOC into its regulation.[21] We reiterate and incorporate herein these comments by reference. OSHA also strongly supported EPA's proposal.[22]

Unfortunately, EPA has not finalized the proposed modifications to its SNUR regulations, precluding EPA from cross-referencing its general SNUR regulations to incorporate the HOC requirement into individual SNURs. Nonetheless, EPA needs to directly incorporate into each SNUR such language and designate failure to follow the HOC as a trigger for notification.

F. EPA should not defer workplace protections to the Occupational Safety and Health Administration (OSHA) or the National Institute for Occupational Safety and Health (NIOSH).

EPA has received comments on other proposed SNURs suggesting that EPA should leave workplace protection to OSHA and NIOSH.[23] EPA should reject this recommendation. EDF has previously commented on why EPA cannot legally transfer its duties to OSHA. To date, EPA has not responded to those comments, or any subsequent comments on the same issue; therefore, EDF's comment remains the same and is reiterated and incorporated herein by reference.[24] Among other issues, we note that:

---

[21] *See* EDF Comments on Significant New Uses of Chemical Substances: Updates to the Hazard Communication Program and Regulatory Framework, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052.

[22] *See* OSHA Comments on Significant New Uses of Chemical Substances: Updates to the Hazard Communication Program and Regulatory Framework, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0041.

[23] *See, e.g.*, ACC Comment on Proposed SNURs for 19 Chemical Substances at 11, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0464-0117; and ACC Comment on Proposed SNURs for 145 Chemical Substances at 11, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0389. We note that some of ACC's comments refer to NIOSH "requirements" – despite the fact that NIOSH is a research agency, not a regulatory agency, and while at times it provides recommendations and guidance, it has no authority to impose workplace requirements.

[24] EDF Comments on New Chemicals at 34-39 (submitted Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071.

- nothing in the statute supports the assertion that EPA should rely on OSHA to regulate new chemicals in the workplace, *see* 15 U.S.C. § 2604(f)(5); and
- due to the limitations on OSHA's authority, the protections for workers would not meet TSCA's requirement to "protect against an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(e).

V. EPA has failed to disclose critical health and safety information.

TSCA does not extend CBI protection to "any health and safety study which is submitted under [TSCA] with respect to *** any chemical substance or mixture *** for which notification is required under section 5." 15 U.S.C. § 2613(b)(2)(A). In addition, TSCA requires disclosure of "any information reported to, or otherwise obtained by, [EPA] from a health and safety study which relates to [such] a chemical substance." *Id*. § 2613(b)(2)(B). Thus, EPA must disclose any health and safety study or other data on health or environmental effects or assessment of risk.

Under section 2(8), TSCA broadly defines the term "health and safety study" as "any study of any effect of a chemical substance or mixture on health or the environment or on both, *including underlying information* and epidemiological studies, studies of *occupational exposure* to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act." 15 U.S.C. § 2601(8) (emphases added). In addition to the scientific analyses developed by EPA (e.g. engineering reports, Structure Activity Team reports), which clearly fall under this definition, this definition includes existing information that is generally required to be submitted with PMNs, such as toxicity studies, information on worker exposure, and the majority of information in Safety Data Sheets (SDSs). EPA must disclose this information to the public.

Despite these mandates, EPA has continued its past practice of failing to disclose health and safety information.[25]

First, EPA's SAT reports, engineering reports, and exposure reports all constitute or contain health and safety information that EPA must disclose, yet in some cases EPA has largely redacted these documents. For example, for P-18-0239 and P-18-0240, EPA redacted most of the Human Health Report, including multiple statements pertaining to exposures.[26] For P-16-

[25] *See, e.g.*, EDF Blog, EPA's appalling failure to provide public access to public data on TSCA new chemicals (published Jan. 24, 2018), http://blogs.edf.org/health/2018/01/24/epas-appalling-failure-to-provide-public-access-to-public-data-on-tsca-new-chemicals/?_ga=2.89078043.1856309501.1537892726-219607077.1531321487.

[26] P-18-0239-240 HEALTH Report Post Focus Final Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0226-0018.

0417, EPA has largely redacted the engineering report, which also largely consists of exposure information.[27]

Second, EPA has also failed to scrutinize a number of plainly illegal redactions by PMN submitters. For example, the list of attachments in the PMN for P-18-0239 and P-18-0240 indicates it is supposed to include a 15-page Pollution Prevention Risk Assessment.[28] Yet the document in the docket associated with this PMN has been condensed to a single page that is entirely redacted.[29]

Public access to the documents described in this section is critical because they contain highly relevant information on hazard and exposure. In order for EDF or other members of the public to comment meaningfully on whether the notification requirements identified by EPA in a SNUR are sufficient, access to the hazard and exposure information EPA considered is necessary. EPA must ensure that the public docket for its proposed SNURs is complete, which includes providing public access to all health and safety information.

In its response[30] to our similar comments on an earlier batch of non-5(e) SNURs, EPA stated (emphasis added):

> EPA recognizes that TSCA Section 14 does not protect from disclosure certain confidential information described in Section 14(b), including health and safety information. However, *Section 14 does not require that EPA make a final confidentiality determination for all information submitted under TSCA and claimed as CBI as part of a PMN review*, and EPA has not made a determination regarding the eligibility for confidential treatment of the information referenced in the comment.

EDF strongly disagrees that TSCA does not require EPA to review and make determinations on CBI claims asserted for information submitted as part of a PMN review. EPA is required to do just that under TSCA section 14(g)(1). The only exceptions to this requirement are for information types falling under section 14(c)(2), which are not applicable to the information we have identified.

---

[27] P-16-0417 ENG Report Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0226-0004.
[28] P-18-0239 and 0240 PMN Sanitized, https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2019-0226-0027&contentType=pdf.
[29] Sanitized P2 Risk Assessment, https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2019-0226-0027&attachmentNumber=12&contentType=pdf.
[30] 84 Fed. Reg. 13531, 13534 (April 5, 2019).

Other than for information that falls under TSCA section 14(c)(2), EPA is required to review "a representative subset, comprising at least 25 percent, of all" CBI claims and make determinations on them within 90 days of receipt of the information bearing the claims. 15 U.S.C. § 2613(g)(1)(A), (1)(C)(ii). For all of these PMNs subject to the proposed SNURs, that 90-day period has long expired. For each PMN, the table below shows the date of PMN receipt and the number of days between that receipt date and the date of publication of these proposed SNURs:

PMN number	**Receipt date of most recent PMN[31]**	**No. of days between date of receipt and date of SNUR proposal (7-8-2019)**
P-16-0417	June 16, 2016	1117
P-18-0239	July 16, 2018	357
P-18-0240	July 16, 2018	357

As shown in the table, for every PMN, far more than 90 days have elapsed between its date of receipt and the date of the current SNUR proposal. EPA has no basis to argue that it should not have long ago reviewed and reached determinations on a representative subset of the CBI claims in the PMNs and associated information submitted with them, other than any information it determined falls under the exceptions provided in TSCA section 14(c)(2).

Moreover, much of the information we have described is health and safety information that is not eligible to be claimed CBI at all under TSCA section 14(b)(2). Any such claims must be rejected outright and need not undergo the mandated review applicable to other types of information submitted during a PMN review.

EPA's response goes on to state:

> With regard to EPA technical support reports underlying the section 5 determination, they are not covered by section 14(b)(2), which specifically refers to health and safety studies submitted to EPA.

This response ignores section 14(b)(2)(B), which excludes from CBI protection "any information reported to, or otherwise obtained by, the Administrator from a health and safety study ***." Unlike section 14(b)(2)(A), this provision is not limited to information "submitted" to EPA. The reports in question are the outputs of health and safety studies EPA has conducted, and hence has obtained. Moreover, the inputs to these analyses are often themselves from health and safety

[31] Where a given PMN is listed in multiple Federal Register notices, we have conservatively indicated the most recent receipt date.

studies, and thus the outputs are also "any information *** otherwise obtained by, [EPA] from a health and safety study" on that basis as well.

VI. The use descriptions provided by EPA for the proposed SNURs are unacceptably broad or vague and do not comply with EPA's own instructions for PMNs.

For each chemical substance subject to a proposed SNUR, the specific use has been claimed confidential and EPA has provided a generic use description. These appear to have been taken directly from the underlying PMNs.

Despite EPA having provided PMN submitters instructions to the contrary, these generic use descriptions are overly broad or vague:

- P-16-0417: Adhesive for open, non-dispersive use
- P-18-0239 and P-18-0240: Reactants in coatings

These generic use descriptions do not comply with EPA's own 2015 *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program*.[32]

The instructions call for the generic use description to include *both* (1) a description of the category of use, which "should reveal the intended category of use to the maximum extent possible;" and (2) a characterization of the "degree of containment," with examples of the latter cited such as "destructive use" or "open, non-dispersive use." Both components are needed; EPA's manual states: "a generic use description that solely describes the degree of containment such as 'open, non-dispersive use' is not acceptable." *Id*. at 46.

None of the generic uses cited above complies with the instructions. For each of these substances, EPA needs to provide sufficiently illuminating generic or specific use descriptions. To the extent that the problems with these descriptions originated with the PMNs themselves, EPA should not have accepted those PMNs in the first place. EPA should certainly have required the submitter to provide a generic or specific use description that complies with EPA instructions, rather than simply accepting and carrying forward such overly broad and vague use descriptions.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

[32] *See* U.S. EPA, *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program* at 46-47 (2015), https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf.