Environmental Defense Fund Comments on
Significant New Use Rules on Certain Chemical Substances
Docket ID: EPA-HQ-OPPT-2018-0772[1]

Submitted May 20, 2019

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on EPA's proposed rules covering 11 significant new use rules (SNURs) addressing 11 chemical substances, *see* 84 Fed. Reg. 16432 (Apr. 19, 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 seven of the PMN substances (determining that each of them is "not likely to present an unreasonable risk"): P-17-0239, P-18-0048, P-18-0073, P-18-0122, P-18-0162, P-18-0222, and P-19-0010.

No final determination has been made for the other four PMN substances (P-14-0482, P-16-0422, P-17-0152, and P-17-0245). As of the date of these comments, none of them is subject to a final TSCA § 5(e) consent order, although such an order was recommended for all four; see "interim status" entry for each PMN in EPA's status table.[2] The absence of any final decision document for these four PMNs describing what if any risk concerns EPA identified necessarily complicated and constrained EDF's ability to comment meaningfully on them.

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

[1] The docket is at https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0772.
[2] The status table is available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and. View a specific PMN by entering the PMN number into the search box at the top of the table.

Contents:

I. 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; and EDF Comments on Significant New Use Rules on Certain Chemical Substances, Docket ID: EPA-HQ-OPPT-2017-05751, submitted November 15, 2018, 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.[3] 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 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 at least seven of them.

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

[3] 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.

II. 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.

Some of EPA's proposed SNURs do not include designation of *any* use that would require notification, and make no reference 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 each of these chemicals. These chemicals and their associated health concerns are as follows:

- P-16-0422: Irritation and sensitization, developmental toxicity, and aquatic toxicity
- P-17-0152: Lung effects and aquatic toxicity
- P-17-0239: Irritation, sensitization, and oncogenicity
- P-18-0122: Irritation to skin, eyes, and lungs, lung toxicity, and aquatic toxicity
- P-18-0162: Pulmonary effects
- P-19-0010: Irritation, sensitization, pulmonary toxicity, mutagenicity, and carcinogenicity

It is not clear from the TSCA section 5(a)(3) determination documents for these PMN chemicals whether EPA assessed any *uses* other than the specific uses identified by the PMN submitters.[4] 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 some of the chemicals discussed in this section of our comments, EPA has included in the SNURs other types of triggers for notification, such as: manufacturing, processing or use that results in inhalation exposure, *see, e.g.*, 84 Fed. Reg. at 16439 (to be codified at 40 C.F.R. § 721.11249 (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[5] 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.

[4] While EPA did identify and evaluate some reasonably foreseen conditions of use for at least some of these chemicals, these reasonably foreseen conditions of use primarily dealt with the *form* or *environmental release* of the chemical substance and not its *use*.
[5] 84 Fed. Reg. 13531, 13534 (April 5, 2019).

This response entirely misses the point. Even were 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 – not illegal, it creates serious potential for a "risk gap" to arise: that is, a failure to evaluate and make a determination for risks associated with conditions of use that EPA did not evaluate in its initial review, and that it will also not evaluate in its future review of any SNUN it receives because the SNUR EPA has promulgated does not identify such conditions of use as a trigger requiring notification. 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.

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

Of the seven PMNs covered by the proposed SNURs for which EPA has made final determinations (all of them "not likely" determinations), EPA found risks to workers for five of them. (For the four PMNs for which final determinations have not been made, we cannot tell whether EPA did or did not identify any such risks.)

The five PMN numbers are listed below along with the identified worker risks:

- P-17-0239: Irritation and sensitization via dermal and inhalation exposures*
- P-18-0048: Reproductive toxicity via dermal exposure; corrosion to all tissues via dermal and inhalation exposures*
- P-18-0073: Liver, kidney and gastrointestinal effects via dermal exposure; irritation and corrosion via dermal exposure*; pulmonary effects via inhalation exposure
- P-18-0122: Lung toxicity via inhalation; irritation to skin, eyes, lung and GI tract*
- P-19-0010: Irritation and sensitization via dermal exposure*

* For these endpoints, EPA did not quantify and/or stated that it could not quantify the magnitude of the risk due to lack of dose-response information.

For three other PMNs covered by these proposed SNURs that do not have final determinations, other documents in the docket indicate that EPA also identified risks to workers, but invoke use of PPE as sufficient to mitigate the risks:

- P-14-0482: Sensitization and developmental toxicity via dermal exposure[6]
- P-16-0422: Development effects via dermal exposure[7]

[6] Premanufacture Notice for (PMN) P14-0482 Health Report Post Focus Final Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0018.
[7] Health and ECO Risk Assessment Post Focus Premanufacture Notice (PMN) P16-0422 Final Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0026.

- P-17-0245: Irritation and sensitization hazards to workers via dermal exposure[8]

In at least seven of these eight cases, and often despite the absence of data that would have allowed EPA to quantify some or all of the risks in each of the cases, 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[9] 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 (where EPA has made such a determination).
- 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.

Unfortunately, for three of the eight PMNs (P-16-0422, P-18-0073, and P-19-0010), EPA has failed to provide a copy of the SDS in its docket even though one was attached to each associated PMN. For three other PMNs (P-14-0482, P-17-0239, and P-17-0245),[10] the SDS EPA included in

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[8] Health Post Focus Report for Premanufacture Notice (PMN) P17-0245 Final Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0101.

[9] 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/; and http://blogs.edf.org/health/tag/myth-busting/. EDF incorporates these comments by reference.

[10] These three totally redacted SDSs are available at https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0772-0002&attachmentNumber=10&contentType=pdf; https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0772-0003&attachmentNumber=2&contentType=pdf; and

the docket is *totally redacted* even though much if not all of its content comprises health and safety information not eligible for CBI protection under TSCA and, for the remainder, there is no evidence EPA has reviewed and approved any CBI claims asserted for the SDS.

In the remaining two cases (P-18-0048 and P-18-0122), unredacted SDSs are available in the SNUR docket.[11]

Below we describe what we found upon examining those two SDSs and the five SNURs for the PMN substances having "not likely" determinations.

A. The SDSs fail to incorporate the PPE specifications EPA describes in the associated "not likely" determination documents.

The following quoted excerpts are all taken directly from the corresponding "not likely to present unreasonable risk" determination document for the PMN substance.[12]

P-18-0048: EPA identifies as "appropriate PPE" the use of "impervious gloves and a respirator." EPA goes on to state:

> EPA expects that employers will require and workers will use appropriate personal protective equipment, including dermal and *respiratory protection with an Assigned Protection Factor* [APF] *of 50, consistent with the Safety Data Sheet submitted with the PMN*, in a manner adequate to protect them. (p. 6, emphasis added)

The associated SDS does recommend wearing "protective gloves," "suitable protective equipment," and "appropriate chemical resistant gloves." Its only reference to respiratory protection, however, is this: "in the case of insufficient ventilation, wear suitable respiratory equipment."

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.

P-18-0122: EPA states:

> Risks will be mitigated if exposures are controlled by the use of appropriate PPE, *including respiratory protection with an APF of 10*. Risks could not be quantified for

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https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0772-0004&attachmentNumber=4&contentType=pdf.

[11] These two unredacted SDSs are available at https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0772-0005&attachmentNumber=3&contentType=pdf and https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2018-0772-0006&attachmentNumber=4&contentType=pdf, respectively.

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

> irritation hazards, but appropriate PPE, including impervious gloves and protective eye wear, would mitigate concerns. EPA expects that employers will require and workers will use appropriate personal protective equipment (i.e., impervious gloves, protective eye wear, and a respirator), consistent with the Safety Data Sheet prepared by the PMN submitter, in a manner adequate to protect them. (pp. 5-6, emphasis added)

While the SDS does recommend certain types of gloves and safety glasses, it specifically states: "Other protective equipment is not generally required under normal working conditions." The only mention of use of a respirator anywhere in the SDS is where an OSHA regulatory workplace standard (TLV, PEL, or STEL) is exceeded – which is clearly not the case here, as no such standards exist for the PMN substance. Nowhere does the SDS specify use of a respirator with an APF of 10. Here again, the SDS is clearly not consistent with EPA's own description of it.

B. The proposed SNURs fail to incorporate the SDSs' recommended protective measures.

P-18-0048: As noted above, the SDS for this substance recommends wearing "protective gloves," "suitable protective equipment," and "appropriate chemical resistant gloves." Its reference to respiratory protection states: "in the case of insufficient ventilation, wear suitable respiratory equipment."

In contrast, the proposed SNUR has no such provisions. The only activity it proposes to designate as a significant new use is to "use the substance other than as an emulsifier for metal working fluid."

P-18-0122: As noted above, the SDS recommends certain types of gloves and safety glasses. It leaves to the "end user [to] determine if the process or methods involved require other personal protection clothing or equipment."

In contrast, the proposed SNUR lacks even these provisions. The only activity it proposes to designate as a significant new use is to "release a manufacturing, processing, or use stream associated with any use of the substances, other than the confidential chemical intermediate use described in the premanufacture notices, into the waters of the United States exceeding a surface water concentration of 1 part per billion (ppb)."

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.[13]

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

P-17-0239: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves, eye protection, and a respirator." The latter is "expected" to be a "NIOSH certified respirator APF 50."

In contrast, the proposed SNUR lacks any such provisions. The only activities it proposes to designate as a significant new use are use in a consumer product, use involving spray application that results in inhalation exposures, manufacture to contain more than 20% residual isocyanate by weight; and release to water above 33 ppb.

P-18-0048: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves and a respirator." The latter is "expected" to be a respirator with an APF of 50.

In contrast, the proposed SNUR has no such provisions. The only activity it proposes to designate as a significant new use is to "use the substance other than as an emulsifier for metal working fluid."

P-18-0073: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves, eye protection, and a respirator with an assigned protection factor of 10."

In contrast, the proposed SNUR lacks any such provisions. The only activities it proposes to designate as a significant new use are uses other than "as a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) inert ingredient, an anti-scalant, chlorine stabilizer, or the additional confidential uses stated in the PMN."

P-18-0122: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves, eye protection, and a respirator." EPA "expects" the respirator to have an APF of 10.

In contrast, the proposed SNUR lacks even these provisions. The only activity it proposes to designate as a significant new use is to "release a manufacturing, processing, or use stream associated with any use of the substances, other than the confidential chemical intermediate use described in the premanufacture notices, into the waters of the United States exceeding a surface water concentration of 1 part per billion (ppb)."

P-19-0010: EPA's "not likely" determination document for this PMN "expects" workers to use "impervious gloves."

In contrast, the proposed SNUR lacks even that provision. The only activity it proposes to designate as a significant new use is to "use the substance involving an application method that results in inhalation exposures."

D. EPA should add provisions addressing "protection in the workplace" and "hazard communication" for eight of the proposed SNURs for which evidence of potential worker risks is present.

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 721.72.14 See, for example, the SNURs codified at 40 CFR § 721.10095 or § 721.11000. None of the proposed SNURs for the eight PMNs in this batch for 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.[15] 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 or on what basis it concluded that the controls identified in footnote 15 will be sufficient to eliminate risks to workers. 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 eight PMNs in this batch for 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,[16] as well as a longstanding foundational element of the Occupational Safety and Health Administration's (OSHA) workplace safety policy[17] and of the National Institute for Occupational Safety and Health's (NIOSH) workplace safety guidance.[18] It gives strong preference to the use of engineering or

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[14] See https://www.law.cornell.edu/cfr/text/40/721.63 and https://www.law.cornell.edu/cfr/text/40/721.72.

[15] It should be noted that for some of the chemicals discussed in this section of our comments, EPA has included in the SNURs other types of triggers for notification, such as: manufacturing, processing or use that results in inhalation exposure, *see, e.g.*, 84 Fed. Reg. at 16439 (to be codified at 40 C.F.R. § 721.11249 (a)(2)(i)). Although EDF supports inclusion of these notification triggers, EPA must also require notification for any manufacturing or processing without *specific* workplace exposure controls unless EPA can determine and publicly justify why those exposure controls are not necessary to ameliorate the risks to workers.

[16] *See* Occupational Safety & Health Admin., *Informational Booklet on Industrial Hygiene* (1998), https://www.osha.gov/Publications/OSHA3143/OSHA3143.htm#How do.

[17] *See* CHEMICAL HAZARDS AND TOXIC SUBSTANCES, CONTROLLING EXPOSURES, https://www.osha.gov/SLTC/hazardoustoxicsubstances/control.html (last visited Sept. 14, 2018).

[18] *See* WORKPLACE SAFETY AND HEALTH TOPICS, HIERARCHY OF CONTROLS, https://www.cdc.gov/niosh/topics/hierarchy/ (last visited Sept. 14, 2018).

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.[19] We reiterate and incorporate herein these comments by reference. OSHA also strongly supported EPA's proposal.[20]

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 recently received comments on other proposed SNURs suggesting that EPA should leave workplace protection to OSHA and NIOSH.[21] 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.[22] Among other issues, we note that:

- 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

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[19] *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.
[20] *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.
[21] 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.
[22] EDF Comments on New Chemicals at 34-39 (submitted Jan. 20, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071.

- 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).

IV. 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.[23]

First, numerous documents submitted as attachments to the PMNs that constitute or contain health and safety information that EPA must disclose are entirely missing from the docket. The list below identifies examples of relevant documents that EPA has not placed in the docket:

- P-16-0422: Safety Data Sheet (SDS)
- P-18-0073: SDS (3 versions), WOE [weight-of-evidence] analysis to support non-sensitizer finding, toxicologist report
- P-18-0222: SDS, acute daphnia test, biodegradation test, algae toxicity test, melting point, study list
- P-19-0010: SDS

[23] *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.

Second, 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-14-0482, EPA redacted most of the engineering report, including multiple statements pertaining to revisions made by the PMN submitter, at least some relating to the chemical's environmental releases or other exposure-relevant information.[24] For P-16-0422, EPA has nearly entirely redacted the document titled "Health Summary Studies," which consists entirely of data extractions from human health studies.[25]

Third, 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-17-0245 indicates it is supposed to include a five-page safety data sheet and the list of attachments for P-16-0422 indicates they are supposed to include at least six toxicity studies totaling 185 pages as well as a six-page safety data sheet.[26] Yet each document in the docket associated with these two PMNs has been condensed to a single page that is entirely redacted.[27]

SDSs contain information regarding hazards and toxicity, accidental release and first-aid measures, fire-fighting methods, handling and storage precautions, needed exposure controls including personal protection, disposal and transport considerations, reactivity and stability, and physical and chemical properties for a chemical substance. It is difficult to understand how any, let alone all, of this information does not constitute or contain health and safety information that cannot be claimed CBI under TSCA. Even if some of the information in an SDS arguably is not health and safety information and is also eligible for confidentiality under TSCA § 14, that is no basis for redacting the entire form, *see* TSCA 15 U.S.C. § 1413(b)(1).

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[28] 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

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[24] Initial Review Engineering Report for Premanufacture Notice (PMN) P14-0482 Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0015.
[25] Post - Focus Data Review Health Report for Premanufacture Notice (PMN) P16-0422 Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0027.
[26] PMN at 31, https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2017-0575-0008&contentType=pdf.
[27] P-16-0422: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0008; P-17-0245: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0004.
[28] 84 Fed. Reg. 13531, 13534 (April 5, 2019).

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.

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*	# of days between date of receipt and date of SNUR proposal (4-19-2019)
P-14-0482	before 6/22/2016	1031
P-16-0422	before 6/22/2016	1031
P-17-0152	11/16/2017	519
P-17-0239	8/11/2017	616
P-17-0245	8/15/2017	612
P-18-0048	11/13/2017	522
P-18-0073	12/19/2018	121
P-18-0122	4/24/2018	360
P-18-0162	12/27/2018	113
P-18-0222	6/22/2018	301
P-19-0010	10/29/2018	172

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

As shown in the table, for every PMN, more – typically 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 studies, and thus the outputs are also "any information *** otherwise obtained by, [EPA] from a health and safety study" on that basis as well.

V. EPA appears to have deviated from its Persistent, Bioaccumulative, and Toxic New Chemical Substances Testing Policy, and failed to explain those deviations.

EPA predicts that one of the PMN substances – P-17-0245 – and/or its degradant is or could be a persistent, bioaccumulative, and toxic substance ("PBT"). Based on its generic name – "unsaturated polyfluoro ester" – the chemical may also be a member of the PFAS family.

As discussed below, EPA appears to have deviated from its New Chemical Program's PBT Category in this case and has failed to acknowledge or explain why it is doing so. *See* 64 Fed. Reg. 60194 (Nov. 4, 1999), https://www.gpo.gov/fdsys/pkg/FR-1999-11-04/pdf/99-28888.pdf (hereinafter "PBT Policy") (adopting criteria for identification of new chemicals as PBTs).

Under the PBT Policy, EPA considers a chemical to be persistent if its biodegradation half-life is greater than 2 months, and to be bioaccumulative if its bioaccumulation factor (BAF) or fish bioconcentration factor (BCF) is greater than or equal to 1,000. PBT Policy at 60202. The PBT Policy also establishes a tiered testing strategy describing test data that EPA "believes are needed to evaluate the persistence, bioaccumulation, and toxicity of a PBT chemical." 64 Fed. Reg. at 60203. Tiers 1 and 2 of the testing strategy focus on determining the biodegradability of the chemical substance. *Id.* Of particular relevance here is tier 3 of the testing strategy, which states that:

> [h]uman health hazards should be determined in the combined repeated dose oral toxicity with the reproductive/developmental toxicity screening test ***.

64 Fed. Reg. at 60203. The PBT policy further states, "tier 3 testing will normally be required" if the "measured biodegradation half-life is > 60 days and measured BCF is > 1,000." *Id.*

For P-17-0245, the preamble to the proposed SNUR states that "the PMN substance is potentially persistent, bioaccumulative, and toxic (PBT) chemical. EPA estimates that the PMN substance will persist in the environment for more than six months and estimates an unknown bioaccumulation factor." EPA also identified several toxicity concerns: for irritation, respiratory sensitization, and mutagenicity.[29]

In the SAT Report and Ecotoxicity Report for this PMN substance, EPA identified it as very persistent and noted that a breakdown product is also very persistent and is of "unknown" bioaccumulation potential and toxicity.[30] It assigned the following scores to the breakdown product:

- Persistence: 3
- Bioaccumulation: unknown
- Toxicity: unknown

EPA has not issued any final determination for this PMN substance, so it is not clear whether EPA intends to require any testing. Given the PBT potential and the clear need for more information to assess breakdown, bioaccumulation potential and toxicity, EPA should issue an order for this substance that requires testing, in keeping with the intent of EPA's PBT policy. If EPA nevertheless chooses not to require testing, EPA must acknowledge and provide an explanation for not doing so. The PBT policy itself states that when EPA departs from the policy, "EPA will explain why a different course was taken." 64 Fed. Reg. at 60204.

More broadly, 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 not to require testing of this PMN substance.

[29] See Preamble, p. 16435.
[30] Structure Activity Team (SAT) Report for Premanufacture Notice (PMN) P17-0245 Sanitized at 2, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0097; and Ecotox Report for Premanufacture Notice (PMN) P17-0245 Sanitized at 3, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0100.

VI. In two proposed SNURs, EPA would allow companies making the PMN substance for the use described in the PMN to release the substance into water at a level that exceeds EPA's concentration of concern (COC) without prior notification.

The proposed SNUR for P-16-0422 states (emphasis added):[31]

> It is a significant new use to release a manufacturing, processing, or use stream associated with any use of the substance, *other than releases from the confidential polymer additive use described in the PMN*, into the waters of the United States exceeding a surface water concentration of 12 part per billion (ppb) using the methods described in § 721.91.

The proposed SNUR for P-18-0122 states (emphasis added):[32]

> It is a significant new use to release a manufacturing, processing, or use stream associated with any use of the substances, *other than the confidential chemical intermediate use described in the premanufacture notices*, into the waters of the United States exceeding a surface water concentration of 1 part per billion (ppb) using the methods described in § 721.91.

In each case, the provision as drafted would allow the PMN submitter or another company to exceed the specified concentration without notifying EPA: As long as the company is making, processing or using the chemical for the use specified in the PMN, the notification trigger would not apply.

In its "not likely" determination document for P-18-0122, EPA states (p. 6; emphases added):

> Risks to the environment were evaluated by comparing estimated surface water concentrations with the estimated acute and chronic concentrations of concern. Risks to the environment were not identified due to releases to water *because relevant surface water concentrations did not exceed the acute or the chronic COCs*.
>
> It is reasonably foreseen that manufacture, processing, or use of the new chemical substance could result in releases to water exceeding the COC of 1 ppb. *It is reasonably foreseen based on the initial PMN submission that included conditions of use resulting in release to water that posed risk to the environment*.

EPA has not provided any basis for expecting that the applicable COC would differ based on use; in fact, EPA acknowledges that the PMN substance *could* be made, processed or used in a manner that *would* exceed the COC. The fact that the PMN has been revised so that EPA believes the PMN submitter's manufacture, processing, or use – if all associated PMN

[31] 84 Fed. Reg 16439, proposed § 721.11248(a)(2)(1).
[32] 84 Fed. Reg 16440, proposed § 721.11254(a)(2)(1).

conditions are fully adhered to – would not result in exceedance of the limit does not alter the COC or the concern about the risks associated with exceeding it.

EPA should not allow a company to exceed the COC without prior notification merely because it is engaging in the same use described in the PMN. Yet that is what the cited SNUR provisions as drafted would allow. In both of these SNURs, EPA needs to subject *all* companies, including the PMN submitter, to the surface water concentration exceedance notification triggers.

VII. For a PMN substance intended for use in consumer products, EPA identified risks to consumers but has not demonstrated why the conditions in its proposed SNUR are sufficient.

P-17-0152 lists its generic use as "an additive in home care products." While no final determination has been made for the chemical, a "Consumer Calculations" document in the docket states:

> Risks were identified for consumers for lung effects (cationic binding) via inhalation based on analogue data (MOEs range from 51-410, depending on proximity to use; Benchmark MOE=1000).[33]

EPA's proposed rule does not mention these risks, nor does it explain how the provisions of the proposed SNUR are sufficient notification triggers to ensure risks to consumers are mitigated.

Moreover, the preamble's description of "protective measures" in the PMN indicates that there will not be manufacture or processing of the substance as a powder or solid (p. 16434). However, no such provision is included as a notification trigger in the proposed SNUR (p. 16439), leaving a clear gap. EPA must include manufacture or processing of the substance as a powder or solid as significant new uses for this chemical; given the preamble, it appears that EPA intended to do so.

Given the dispersive nature of this PMN substance's intended use, EPA needs to provide far more explanation as to the nature and extent of such risk and why the risk will be sufficiently mitigated by the limited provisions in the SNUR. EPA also needs to ensure the SNUR includes as notification triggers all of those manufacturing, processing and use restrictions in the PMN on which it intends to rely in making a final determination on this PMN.

[33] Focus Updated Consumer Calcs October 3, 2018 Hazard Update December 19, 2018 for Premanufacture Notice (PMN) P17-0152 Sanitized at 2, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0772-0030.

VIII. EPA must place restrictions on residual isocyanates in the PMN substances where they may present an unreasonable risk to human health.

Three of the PMN substances in this proposed rule are or appear to be manufactured using isocyanates: P-17-0239, P-18-0162, and P-19-0010. In previous SNURs, EPA has included a provision that designates exceeding a specified weight percent of 0.1% for residual isocyanates in the PMN chemical substance be a significant new use. See, for example, 84 Fed. Reg. at 10016 (40 C.F.R. § 721.11237(a)(2)(iii)); 84 Fed. Reg. at 10018 (40 C.F.R. § 721.11242(a)(2)(iii)). EDF supported those designations of significant new uses and commented on why it is appropriate for EPA to regulate the risks associated with residual isocyanates. EDF fully incorporates and reiterates those comments here by reference. *See, e.g.*, EDF's Comment at 14, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0567-0167.

However, in the SNURs for these three PMNs involving isocyanates, EPA has not included such a trigger for notification.[34] Given the clear hazards and potential risks associated with the presence of any residual isocyanate, EPA needs to add to these SNURs a notification requirement triggered by any exceedance of a weight percent of 0.1% for residual isocyanates to ensure it reviews any circumstance where that level could be exceeded.

IX. EPA must ensure that the generic names in the proposed SNURs comply with the requirements of TSCA and EPA's guidance.

EPA has accepted and is using generic names for two PMN substances in this batch of proposed SNURs that are not or appear not to be consistent with the requirements of TSCA § 14(c)(1)(C) or with EPA's *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting Under the Toxic Substances Control Act* (hereinafter "Generic Name Guidance").[35] Specifically, when asserting the claim for confidentiality for a specific chemical identity, TSCA requires that:

> [T]he claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—
> (i) be consistent with guidance developed by the Administrator under paragraph (4)(A); and
> (ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—

[34] All three chemical substances have other triggers in the proposed SNURs that may be relevant to the potential risks from isocyanates, but EPA has not explained whether or why they are sufficient. Unless EPA can determine and publicly justify why a residual isocyanate trigger is not necessary to ameliorate the risks, including to workers, EPA must include a notification trigger for residual isocyanate in the proposed SNURs for all three chemical substances.
[35] EDF has previously submitted comments addressing EPA's implementation of TSCA's requirements on generic names and on EPA's Generic Name Guidance. EDF Comment on Generic Name Guidance, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0292-0006. EDF incorporates those comments in full here.

(I) that are claimed as confidential; and
(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

15 U.S.C. § 2613(c)(1)(C).

Thus, generic names must "describe the chemical structure of the chemical substance as specifically as practicable." *Id.* In addition, claimants must claim specific features of the chemical as confidential and those features may only be those "the disclosure of which would be likely to cause substantial harm to the competitive position of the person." *Id.* EPA's Generic Name Guidance also states that if the PMN submitter "feel[s] that it will be necessary to mask more than one structural element of a specific chemical name in order to mask a confidential chemical identity" the submitter should consult with EPA. Generic Name Guidance at 2.

Despite TSCA's requirement for generic names to be as specific as practicable, and EPA's stated preference in its guidance for masking only a single structural element, we have identified at least two generic names covered by the proposed SNURs (there may be more than these two) that are not or may not be sufficiently specific to comply with either TSCA or EPA's guidance:

- P-14-0482: Organic salt
- P-17-0245: Unsaturated polyfluoro ester

Prior to finalizing this batch of SNURs, EPA must ensure that the generic names for the associated chemicals comply with the law and conform to EPA's guidance. EPA should fully explain why and how any of these names it retains do comply.

Where these names are overly generic, it is not clear why EPA did not challenge such overly generic names for the chemicals earlier in the process. They should have been questioned immediately upon EPA's receipt of the PMNs identifying the chemicals using those generic names, rather than persisting through the PMN review and SNUR development processes.

EDF is concerned that EPA's allowance for overly generic names is indicative of a broader or even systemic problem at EPA with regard to its scrutiny of PMNs and decisions that affect how EPA publicly describes new chemicals with confidential specific identities.

X. Numerous 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 where the specific use has been claimed confidential, 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, a number of these generic use descriptions are overly broad or vague. Consider these examples:

- P-14-0482: Industrial chemical
- P-16-0422: Additive for polymers
- P-17-0152: Additive in home care products
- P-18-0073: Non-pesticide agricultural use chemical
- P-18-0122: Paper additive
- P-18-0162: Adhesive component
- P-19-0010: Adhesive

These generic use descriptions do not comply with EPA's own 2015 *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program*.[36]

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 examples of generic uses cited above complies with the instructions. For each of the substances subject to a SNUR, 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.

[36] *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.