

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## Comments of Safer Chemicals Healthy Families and other Organizations on Proposed Significant New Use Rules on Certain Chemical Substances under Section 5 of the Amended Toxic Substances Control Act

Submitted via Regulations.gov (November 15, 2018)

Docket ID EPA-HQ-OPPT-2017-0575

Safer Chemicals Healthy Families (SCHF) and Natural Resources Defense Council (NRDC) submit these comments on the Environmental Protection Agency's (EPA) proposed significant new use rules (SNURs) for 13 chemical substances under section 5(a)(2) of the Toxic Substances Control Act (TSCA). 83 Fed. Reg. 52,179 (October 16, 2018).

Our organizations are committed to assuring the safety of chemicals used in our homes, workplaces and in the many products to which our families and children are exposed each day. During the legislative process to amend TSCA, we worked hard to maximize public health protections and to assure that EPA has the necessary authority to evaluate and eliminate the risks of unsafe chemicals. We strongly support a proactive approach to implementing the new law that uses the improved tools that Congress gave EPA to deliver significant health and environmental benefits to the American public.

Section 5 of TSCA performs the core function of ensuring that the hundreds of new chemicals introduced each year do not enter commerce without a careful evaluation to ensure that they do not pose an unreasonable risk to public health and the environment. Where these chemicals raise concerns, section 5 requires EPA to use its essential authority to control their risks and require testing before they harm people and natural systems.

In the 2016 Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (LCSA) amending TSCA, Congress strengthened the section 5 program significantly. These amendments require EPA to make an *affirmative determination of the potential risks of every new chemical* before it can enter commerce. They also increase EPA's authority to protect against risks of new chemicals and to require industry to conduct testing to better understand how new chemicals affect people and the environment. For two years after LCSA's enactment, EPA staff largely implemented the new law as intended, resulting in more thorough evaluations of new chemicals, greater protection against their potential risks, and increased testing to determine their health and environmental effects.

In the face of industry opposition to a strong new chemicals program, however, EPA management is now reversing this progress through a series of steps to dismantle a long-standing PMN review process and replace it with one that is both unlawful and significantly less protective of health and the environment. The proposed SNURs are among the recent steps EPA has taken to circumvent the law and weaken the program.

EPA's initial reviews of the premanufacture notices (PMNs) for the 13 SNUR chemicals identified numerous health and/or environmental concerns that the Agency concluded may result in harm to

workers, other human populations, or the environment under the conditions of use described in the PMNs. Under the PMN review process that EPA applied under the old law and during the first two years of implementing the new law, EPA would have concluded that these chemicals “may present an unreasonable risk of injury” and lack “sufficient information” for determining their effects on health and the environment. Based on these conclusions, it would have issued orders under section 5(e) imposing enforceable restrictions on manufacture, processing, and use of those chemicals and requiring testing in order to address their potential risks.

However, instead of following this well-established path, EPA asked the submitters to amend their PMNs to incorporate voluntary measures that the Agency believed would protect against potential risks and treated these measures as “intended” conditions of use. It then determined that the PMN substances were “not likely to present an unreasonable risk of injury” under section 5(a)(3)(C), have sufficient information to determine their adverse effects, and need not be regulated under section 5(e). However, recognizing that manufacture and processing without applying the voluntary measures in the amended PMNs could present significant risks, EPA treated these activities as “reasonably foreseen” conditions of use and decided to address them through SNURs. The proposed SNURs would define failure to use these voluntary measures as “significant new uses” requiring notification of EPA at least 90 days before these “uses” commence. However, the SNUR provisions would provide significantly less protection of health and the environment than the section 5(e) orders that TSCA requires.

As we show in these comments, the “not likely” determinations underlying the SNURs are legally and scientifically flawed; the law instead requires EPA to restrict the SNUR chemicals under section 5(e) orders. Moreover, in comparison with section 5(e) orders, the proposed SNURs fail to adequately protect health and the environment, underscoring their insufficiency under TSCA. EPA should therefore withdraw both the “not likely” determinations and proposed SNURs and replace them with fully protective section 5(e) orders and new SNURs based on the requirements of those orders.

Apart from these flaws, the proposed SNURs do not provide the public with adequate notice and an opportunity to comment because of the extensive redaction of confidential business information (CBI) from the “not likely” determinations and key support documents in the rulemaking record. In order to enable meaningful public comment on the proposed SNURs, EPA must extend the comment deadline and make available to interested parties CBI that is essential to understand the basis for the proposals and develop informed comments.

**Part I** of the comments expresses serious concern about the lack of a transparent public process for EPA’s radical new policies for PMN review. The non-5(e) SNUR approach that EPA is now implementing was previously outlined in EPA’s 2017 *New Chemicals Decision-Making Framework*. Our organizations and others submitted detailed comments identifying the many flaws in the Framework and requested that EPA review and address the comments before taking any further action. EPA has ignored this request, pressing forward with implementation without finalizing the Framework, responding to comments, or even providing a schedule to do so. At the same time, EPA has afforded the public no opportunity to comment on specific “not likely” determinations issued under the Framework. EPA’s secrecy and persistent indifference to public input has resulted in a far-reaching overhaul of a key TSCA program behind closed doors, with industry influencing policymaking but other stakeholders left in the dark.

**Part II** of the comments shows that TSCA explicitly requires issuance of a section 5(e) order where EPA determines that a new chemical’s “intended” or “reasonably foreseen” conditions of use satisfy the criteria for regulation in section 5(a)(3)(B). There is thus no basis for EPA’s position that reasonably foreseen conditions of use can be disregarded in determining the need for a section 5(e) order. Nor does the law allow EPA to substitute a SNUR for a section 5(e) order where reasonably foreseen conditions of use may present an unreasonable risk of injury. Nowhere does the statute exempt chemicals from determinations under section 5(a)(3)(B) that otherwise trigger section 5(e) orders because EPA intends to issue SNURs. Moreover, SNURs are not equivalent to section 5(e) orders but are less effective in protecting health and the environment from new chemical risks. SNURs are optional, not mandatory, and need not be finalized by any deadline; they impose notification requirements, not regulatory restrictions; and there is no prescribed level of protection that SNURs must afford. Nor are SNURs a vehicle for requiring testing, an essential element of section 5(e) orders where available information is insufficient for evaluating a chemical’s health or environmental effects.

**Part III** shows that, apart from these basic legal shortcomings, the proposed SNURs have limited, bare-bones provisions that will be insufficient in implementing protections for health and the environment under the wide range of conditions under which the SNUR chemicals may be manufactured, processed and used. For several of the SNUR chemicals, EPA identified the potential for serious health effects coupled with exposure by workers under the intended and reasonably foreseen conditions of use. Yet the SNURs lack worker protection and hazard communication programs to ensure that risks to workers and the public from downstream activities are identified and addressed. EPA also found that that several SNUR chemicals are likely to have adverse environmental effects and that discharges to water must be stringently controlled. Yet the SNURs fail to provide notice to downstream processors and users of the PMN substance’s environmental hazards and EPA’s required limits on releases to water and even make it impossible to determine the existence of these limits because the identity of the SNUR chemical is CBI.

Finally, **Part IV** shows that the large amount of information redacted as CBI in the rulemaking record, the “not likely” determinations and the proposals themselves has prevented interested parties from understanding the basis for the proposals and frustrated the preparation of informed comments. EPA must review whether the CBI claims have been adequately substantiated and justify confidential treatment under TSCA. Information undeserving of CBI protection should be added to the record. Using its authority under section 14(d)(7) of TSCA, EPA must also make information that remains redacted as CBI available to interested parties under appropriate safeguards and extend the comment period so there is an opportunity to review and address this vital information.

**I. EPA’S RADICAL NEW POLICIES FOR PMN REVIEW HAVE BEEN ADOPTED AND IMPLEMENTED WITHOUT A TRANSPARENT PUBLIC PROOCCESS**

EPA’s intent to bypass section 5(e) orders and issue SNURs for new chemicals raising health or environmental concerns was first described in its November 2017 *New Chemicals Decision-Making Framework* (Framework). At EPA’s December 6, 2017 public meeting and then in written comments submitted on January 20, 2018, our organizations demonstrated that this approach was unlawful under TSCA and would seriously weaken protection of health and the environment.

On December 11, 2017, we asked EPA to delay implementation of the Framework until it had reviewed and addressed our concerns. EPA ignored this request. Now EPA has begun implementing the Framework through a combination of “not likely” determinations under section 5(a)(3)(C) and SNURs but has not finalized the Framework, responded to the many comments it received, or even provided a schedule for doing so. This – coupled with EPA’s opposition to judicial review of the Framework<sup>1</sup> – has effectively shut the public out of the process and made the Framework a *fait accompli*.

At the same time, EPA has afforded the public no opportunity to comment on the specific “not likely” determinations that form the basis for the proposed SNURs and implement the Framework. Nor has EPA created dockets that provide the underlying analyses and supporting data for these determinations. While some relevant documents have been included in the rulemaking record for the proposed SNURs, these documents have been heavily redacted due to CBI claims and, as a result, are largely incomprehensible and uninformative.

EPA’s extreme secrecy and camouflaging of far-reaching legal and policy changes have prevented meaningful public oversight of an important program impacting thousands of chemicals and the safety of millions of citizens. While industry has exerted considerable influence on EPA’s decisions behind the scenes, the public has lacked a seat at the table and been denied a forum for its concerns. EPA must restore transparency to the PMN program by suspending changes to its established review process until they have been fully vetted by the public in a meaningful notice-and-comment process and the Agency has considered and responded to stakeholder input.

## **II. EPA’S RELIANCE ON SNURs IN LIEU OF SECTION 5(e) ORDERS FOR NEW CHEMICALS OF CONCERN VIOLATES TSCA**

EPA’s initial reviews of the PMNs for the 13 SNUR chemicals identified numerous health and/or environmental concerns that the Agency concluded may result in harm to workers, other human populations or the environment under the conditions of use described in the PMNs. Under the PMN review process that EPA applied under the prior version of TSCA and during the first two years following enactment of LCSA, EPA would have concluded that these chemicals “may present an unreasonable risk of injury” and lack “sufficient information” to determine their health and environmental effects. It would then have issued orders under section 5(e) imposing enforceable restrictions on manufacture, processing and use and requiring testing in order to assess and eliminate their potential risks.

However, instead of following this well-established path, EPA asked the PMN submitters to amend their PMNs to incorporate voluntary measures that the Agency believed would protect against potential risks and treated these measures as “intended” conditions of use. It then determined that the PMN substances were “not likely to present an unreasonable risk of injury” under section 5(a)(3)(C), permitting the PMN submitters to commence production and use of potentially unsafe chemicals without restriction. EPA acknowledged that the manufacture and processing of the chemicals without

---

<sup>1</sup> NRDC and SCHF petitioned for judicial review of the Framework but EPA opposed review on the ground that the Framework was not a final agency action and was not being implemented by the Agency. In its brief and in a declaration by OPPT Director Morris, EPA represented that it had not issued any SNURs for chemicals subject to “not likely” determinations under section 5(a)(3)(C) and was continuing to consider “reasonably foreseen” conditions of use in making such determinations. Only after petitioners sought dismissal on the basis of these representations did EPA start issuing non-5(e) SNURs under the Framework.

these voluntary measures was a “reasonably foreseen” condition of use that posed risks to health and/or the environment. However, rather than issuing the Section 5(e) orders that TSCA requires where substances “may present an unreasonable risk of injury,” EPA proposed SNURs requiring notification of the Agency at least 90 days before these reasonably foreseen uses commence under section 5(a)(2) of TSCA.

The proposed SNURs are unlawful because the underlying “not likely” determinations on which they are based are in violation of TSCA. We request that EPA withdraw both the SNURs and determinations and replace them with section 5(e) orders and then with SNURs extending the requirements of these orders to other manufacturers and processors.

**A. EPA Must Issue Section 5(e) Orders When It Identifies Conditions of Use that May Present an Unreasonable Risk of Injury**

Section 5(a)(3)(C) specifies that a determination that a substance is not likely to present an unreasonable risk of injury must be made “under the conditions of use” of the substance. 15 U.S.C. § 2604(a)(3)(C). Similarly, section 5(e)(1)(A), which describes the orders that EPA must issue where it makes one of the determinations in sections 5(a)(3)(B), requires that such orders “shall” –

prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or . . . prohibit or limit any combination of such activities to the extent necessary to *protect against an unreasonable risk of injury to health or the environment . . . under the conditions of use* (emphasis added).

*Id.* at § 2604(e)(1)(A). As defined in 3(4) of TSCA, “conditions of use” comprise the circumstances under which a chemical is “intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” *Id.* at § 2602(4).

Thus, the determinations EPA makes under section 5(a)(3) must be based on the PMN’s potential for risk from not just the “intended” activities of the PMN submitter but from other activities that are “known” or “reasonably foreseen” during any stage of the chemical’s life-cycle (i.e., manufacture, processing, distribution in commerce, use or disposal). For example, if EPA determines under section 5(a)(3)(B)(i)-(ii) that a new chemical “may present an unreasonable risk of injury” under “reasonably foreseen” conditions of use or that “insufficient information” is available to determine its health and environmental effects, the statute states that EPA “shall take the actions” required under section 5(e). These actions must require development of any necessary information to determine the substance’s adverse effects and protect against any unreasonable risk under the conditions of use, including both “intended” and “reasonably foreseen” circumstances of the chemical’s manufacture, use and disposal if they may present such risks.

EPA’s position that it may base “not likely” determinations under section 5(a)(3)(C) only on “intended” conditions of use and address concerns with “reasonably foreseen” conditions of use through SNURs flies in the face of the express statutory language requiring EPA to consider *all* the conditions of use in section 5(a)(3) determinations. Where these conditions of use raise health or environmental concerns, or EPA lacks sufficient information to determine the chemical’s adverse effects, it cannot make a

determination that the chemical is “not likely to present an unreasonable risk.” Rather, the statute provides only one path – to issue a section 5(e) order.<sup>2</sup>

#### **B. EPA’s Position Is in Conflict with the Legislative History of the Amended Law**

In a floor statement on June 7, 2016, four leading Democratic Senators who spearheaded TSCA reform legislation emphasized EPA would now “make an affirmative finding regarding the chemical’s or significant new use’s potential risks as a condition for commencement of manufacture for commercial purposes.”<sup>3</sup> They stressed that, where EPA “lacks sufficient information to evaluate” the new chemical’s risks or finds that it “does or may present an unreasonable risk, [the Agency] *is obligated to issue an order* or rule that precludes market entry or imposes conditions sufficient to prevent an unreasonable risk” and “can also require additional testing.”<sup>4</sup> 162 Cong. Rec. S3516 (June 7, 2016) (emphasis added).

In comments filed with EPA on January 17, 2017, three of these Senators explicitly rejected EPA’s assertion that “reasonably foreseen” conditions of use are outside the scope of PMN reviews:

Congress clearly intended for EPA to assess *all* conditions of use for new chemicals. Doing otherwise would be antithetical to the goal of providing the assurance that a new chemical proposed for manufacture is not likely to pose an unreasonable risk, whether that risk is presented by the use(s) the first manufacturer intends to commercialize or by a future use commercialized by that or any other manufacturer. The definition of “conditions of use” clearly requires EPA to contemplate such potential future (reasonably foreseen) uses. *If EPA makes a determination that any condition of use, including a reasonably foreseen use, presents or may present an unreasonable risk, or if there is insufficient information with which to make such a determination, sections 5(e) and 5(f) require EPA to issue an order to mitigate the risks from all such uses.*<sup>5</sup>

#### **C. The Law Precludes Issuance of SNURs in Lieu of Section 5(e) Orders for Chemicals That May Present an Unreasonable Risk under Their Conditions of Use**

Nowhere does the statute exempt chemicals from determinations under section 5(a)(3)(B) that would otherwise trigger section 5(e) orders because EPA intends to issue SNURs. And nowhere does the

---

<sup>2</sup> In cases where the evidence shows that the chemical does in fact present an unreasonable risk rather than may present such a risk, EPA would need to make a determination to that effect under section 5(a)(3)(A) and issue a rule or order regulating the chemical under section 5(f). EPA has used these provisions on very few occasions.

<sup>3</sup> In referring to a “significant new use,” these statements have in mind the filing of a notice before undertaking activities triggering notification under a SNUR. Under the new law, these notices would then require safety determinations under section 5(a)(3) that could lead to section 5(e) orders, similar to the process following submission of a PMN for a new chemical.

<sup>4</sup> In context, the reference to a “rule” means a rule imposed under section 6(a) pursuant to section 5(f) which regulates chemicals determined under section 5(a)(3)(A) to present an unreasonable risk. The reference is not to SNURs that impose restrictions in lieu of section 5(e) orders, as contemplated by the Framework.

<sup>5</sup> Senators Markey, Udall and Merkley Comments on “New Chemicals Review Program under the Amended Toxic Substances Control Act”, IAD EPA-HQ-OPPT-2016-0658-0024 (emphasis added). The Senators’ comments also note that “as we negotiated the final bill provisions, we considered – and rejected – language that would have limited EPA’s consideration of the potential for an unreasonable risk to be posed by a chemical substance for which a pre-manufacturing notice was submitted to the specific uses identified by the manufacturer in that notice.”

statute provide that the possible promulgation of a SNUR is a justification for a “not likely” determination under section 5(a)(3)(C).

By their terms, the SNUR provisions in section 5(a)(2) of TSCA do not apply to “new chemical substances” and thus come into play *after* a chemical has completed PMN review.<sup>6</sup> Rather, Congress expressly contemplated the use of SNURs in conjunction with, and not instead of, Section 5(e) orders. Section 5(f)(4) of the amended TSCA codifies EPA’s practice under the original law by requiring the Agency, within 90 days after issuing an order under section 5(e), to either initiate a rulemaking to incorporate the order’s provisions in a SNUR or publish a Federal Register notice describing its reasons for not initiating such a rulemaking. 15 U.S.C. § 2604(f)(4). Thus, Congress envisioned SNURs as filling a regulatory gap *after* a section 5(e) order is in place by applying its restrictions to other manufacturers and processors who are not bound by the order. This concept of SNURs is inconsistent with EPA’s position that SNURs can substitute for section 5(e) orders in the first instance. If Congress had intended that result, section 5(f)(4) would have so stated, but it makes no mention of the issuance of SNURs for new chemicals in the absence of section 5(e) orders.<sup>7</sup>

#### **D. SNURs Do Not Provide Important Protections that must be included In Section 5(e) Orders**

Section 5(e) orders are not only legally required for PMNs that raise health or environmental concerns, but also perform key protective functions in addressing new chemical risks that are not served by SNURs. Thus, as discussed below, a PMN program primarily utilizing SNURs will fall short in achieving the goals of the TSCA new chemical requirements:

- The required level of protection under section 5(e) orders is defined in the statute: orders must prohibit or limit activities involving the restricted chemical “to the extent necessary to protect against an unreasonable risk of injury to health or the environment.” Section 5(f)(4) provides that, where EPA has issued a section 5(e) order, follow-up SNURs must designate as significant new uses “any manufacturing, processing, use, distribution in commerce or disposal of the chemical substance that does not conform to the restrictions imposed by the . . . order.” By contrast, the criteria for SNURs in section 5(a)(2) are amorphous and give EPA discretion in determining which activities will be subject to notification and to what extent they will be restricted. And since EPA would be developing SNURs for chemicals that it has determined “are unlikely to present an unreasonable risk of injury” under section 5(a)(3)(C), there would be no risk findings to shape the selection of control measures.
- By the explicit terms of Section 5(e), orders must “take effect upon the expiration of the applicable review period” and thus will impose restrictions on the PMN submitter as of the date

---

<sup>6</sup> “New chemical substance” is defined in section 3(11) of the law and appears in the PMN requirements of section 5(a)(1)(A)(i) but not in the SNUR provisions of section 5(a)(1)(A)(ii).

<sup>7</sup> EPA regulations provide a mechanism for issuing SNURs for section 5(e) and non-5(e) chemicals that have completed PMN review. 40 C.F.R. Part 721. These regulations were developed under the old law and thus did not reflect the broad definition of “conditions of use” in amended TSCA or its shift to non-discretionary section 5(e) orders in place of those that EPA “may” issue. Given this strengthening and broadening of EPA’s order authority, Congress may have concluded that there was no longer any need for EPA to issue SNURs for non-5(e) chemicals. In any event, 40 C.F.R. 721.170, which governs non-5(e) SNURs, is entitled *Notification requirements for selected new chemical substances that have completed premanufacture review* and thus could not be used while the PMN is pending (as EPA proposes) to restrict activities of the PMN submitter that could be addressed in a section 5(e) order.

it is eligible to begin manufacture. However, unless a 5(e) order has been issued, there is no required timetable in the law for promulgating a SNUR. In this instance, the SNURs for the 13 chemicals were proposed at the same time EPA issued “not likely” determinations but there is no assurance it will do so in the future. Nor is there any requirement that, once proposed, SNURs must be finalized. Should the final SNUR be delayed, the new chemical could be manufactured without any controls or restrictions for an extended period. EPA has already failed to initiate SNUR rulemakings on several section 5(e) chemicals within 90 days of issuance of an order, as required by section 5(f)(4) of TSCA. Thus, it is doubtful whether EPA will expeditiously propose and finalize SNURs on all non-5(e) chemicals going forward.

- SNURs are fundamentally notification requirements. The activities they define as “significant new uses” are not prohibited: companies seeking to conduct these activities must notify EPA and the Agency may decide not to take regulatory action based on information in the notice. By contrast, the requirements imposed by section 5(e) orders are binding on the submitter until and unless EPA decides to modify the order.
- Under section 5(e)(1)(A), where a section 5(e) order is warranted, its requirements must protect against “an unreasonable risk to a potentially exposed or susceptible subpopulation.” Further, in determining the need for a 5(e) order, TSCA requires EPA to evaluate the new chemical’s risks “without consideration of costs or other nonrisk factors.” In contrast, no such language appears in the statutory provisions governing the issuance of SNURs.
- Previous section 5(e) orders typically imposed both controls on exposure and requirements to conduct testing, consistent with determinations under section 5(a)(3)(B) that the information available to the Agency was “insufficient to permit a reasoned evaluation of the health and environmental effects of the” new substance. However, when it bypasses section 5(e) by making a “not likely to present” determination under section 5(a)(3)(C), the Agency would have no obligation to include testing provisions in SNURs. The proposed SNURs for the 13 chemicals, for example, do not include any testing requirements although there is little test data on the SNUR chemicals and testing would provide a better understanding of the potential hazards identified by the Agency. An across-the-board shift from section 5(e) orders to SNURs would therefore mean much less testing for new chemicals of concern, despite the intent of the amended law to increase such testing.<sup>8</sup>
- EPA’s “boilerplate” section 5(e) order allows it to impose additional restrictions and controls based on new evidence of risk.<sup>9</sup> No comparable mechanism exists for SNURs. Instead, if EPA wants to tighten the restrictions in a SNUR, it must conduct a rulemaking to amend the SNUR. Moreover, where the activity to be restricted by the amended SNUR is already occurring, it cannot be designated a new use and the Agency would lack authority to restrict it under the SNUR.

In short, the differences between section 5(e) orders and SNURs go to the heart of the level of protection that EPA affords against the health and environmental risks of new chemicals – a further reason why the proposed SNURs and underlying “not likely” determinations were in violation of TSCA.

---

<sup>8</sup> EPA could address this gap by issuing a section 4 order or rule in conjunction with the SNUR, as it has done previously. However, this EPA has thus far shown no inclination to use its section 4 testing authority.

<sup>9</sup> <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-program-boilerplates>

### **III. THE PROPOSED SNURS LACK RUDIMENTARY PROVISIONS TO NOTIFY PROCESSORS AND USERS OF EPA'S HEALTH AND ENVIRONMENTAL CONCERNS AND MEASURES TO CONTROL EXPOSURE AND ENVIRONMENTAL RELEASE**

In addition to EPA's reliance on legally unjustified "not likely" determinations, the limited, bare-bones provisions of the proposed SNURs will be insufficient in implementing protections for health and the environment under the wide range of conditions under which the SNUR chemicals may be manufactured, processed and used. The inadequacies of these proposed SNURs when compared to the more detailed, enforceable and protective provisions in typical section 5(e) orders underscores why SNURs are a poor substitute for these orders in regulating new chemicals of concern.

#### **A. The SNURs Lack Worker Protection and Hazard Communication Programs to Ensure that Risks to Workers and the Public from Downstream Activities Are Identified and Addressed**

Four of the SNUR chemicals (P-16-0354, P-16-0355, P-16-0483 and P-16-0484) were determined to be linked to serious potential health effects, including irritation of skin, eyes and the respiratory tract, systemic effects on kidneys and spleen, blood clotting, lung toxicity, reproductive toxicity and developmental toxicity. EPA's "not likely" determinations for these chemicals found that some workplace operations under intended conditions of use would result in exposures with Margins of Exposure (MOEs) lower than the "benchmark" MOEs likely to protect workers from harm. Despite these unsafe exposures, the "not likely" determinations did not impose any enforceable worker protections. Likewise, the proposed SNURs for these four chemicals do not include worker protection requirements. As a result, other manufacturers, processors and users of these chemicals will receive no notice of potential risks to health. Because their activities may involve larger exposed populations and higher levels of exposure, MOEs for workers may be lower and more people may be at risk of adverse effects than under the intended conditions of use. However, in the absence of any notice of worker risks or requirements to implement engineering controls or personal protective equipment, the SNURs would not eliminate these risks.

Moreover, while the "not likely" determinations for these chemicals conclude that there will be no meaningful consumer or general population exposure under intended conditions of use, this may not be true for activities of other manufacturers, processors and users which result in broader distribution of the chemical through products or dispersive applications that involve widespread releases into the environment. Yet the absence of notification requirements or other limitations in the SNURs will mean that these potentially unsafe exposure scenarios will not be identified or controlled. Section 5(e) orders would prevent this situation by ensuring that notice of potential risks and required limits on exposure are communicated throughout the new substance's chain of distribution and then implemented.

The "not likely" determinations for several of the SNUR chemicals (P-16-192, P-16-380, P-16-381, P-16-382, P-16-383, P-16-384, P-16-385, P-16-575 and P-16-581) found that these chemicals pose a risk of adverse lung effects. To address these risks, the proposed SNURs would define uses allowing either inhalation of the PMN substance or exposure to it in respirable form as "significant new uses" requiring notification. However, there is no mechanism in the proposed SNURs by which manufacturers of these chemicals would be required to notify processors and users of potential lung toxicity and the necessary measures to prevent inhalation exposure. Adding to this information void, the identities of these chemicals and even some of the SNUR requirements have been declared CBI and, thus, purchasers

of the chemicals would have no practical ability to determine whether they are subject to the SNURs. Thus, compliance with SNUR requirements is extremely unlikely. By contrast, section 5(e) orders would require the manufacturer to notify processors and users of their applicability to the substance as distributed in commerce and obtain agreements by these entities to implement the orders' restrictions.

**B. The SNURs Fail to Provide Notice to Downstream Processors and Users of the PMN Substance's Environmental Effects and EPA's Required Limits on Releases to Water**

Several of the proposed SNURs (P-16-483, P-16-484, P-16-380, P-16-381, P-16-382, P-16-383, P-16-384, and P-16-385) set limits on the concentrations of the SNUR chemical that may be discharged to water based on significant ecotoxicity concerns identified in the "not likely" determinations. Thus, other manufacturers, processors and users of the SNUR chemicals must either comply with these discharge limits or submit notices to EPA before discharges occur. However, unlike section 5(e) orders, the proposed SNURs contain no requirement for manufacturers to notify downstream processors and users of ecotoxicity concerns and required limits on water discharges. Coupled with CBI protections of these chemicals' precise identities, this lack of notice will often mean that processors and users are unaware of, and cannot find out about, water discharge limits and therefor will not implement them.

In short, the proposed SNURs are unlawful and under-protective. In order to satisfy TSCA's requirements and adequately protect the public, EPA must withdraw the "not likely" determinations and SNUR proposals for the 13 chemicals, issue section 5(e) orders, and then issue SNURs extending the requirements of these orders to other entities under section 5(f)(4).

**IV. THE PROPOSED SNURS FAIL TO PROVIDE ADEQUATE NOTICE AND AN OPPORTUNITY TO COMMENT BECAUSE OF THE EXTENSIVE REDACTION OF CBI THAT IS ESSENTIAL TO UNDERSTANDING THE BASIS FOR THE PROPOSALS**

Large amounts of information have been redacted as CBI from the rulemaking record, the "not likely" determinations, and the proposed SNURs themselves, preventing interested parties from understanding the full basis for the proposals and frustrating the preparation of informed comments. EPA must make the redacted CBI available to interested parties under appropriate safeguards and extend the comment period so there is an opportunity to review and address this vital information.

As noted above, the precise identities of all the SNUR chemicals have been withheld as confidential and only generic names have been made available. Extensive use and processing information has been redacted from the PMNs and the descriptions of intended and reasonably foreseen conditions of use in the "not likely" determinations and proposed SNURs are extremely vague. For some chemicals, the analogues on which EPA based its analysis of health and environmental effects were deemed CBI and thus the appropriateness of the analogue and why it was chosen over other possible analogues cannot be assessed. In some of the proposals, even the significant new use definitions are treated as CBI because they would reveal information about engineering controls or uses that were claimed CBI in the PMNs. While the rulemaking record includes several EPA technical documents that reflect the analyses underlying the PMN reviews and "not likely" determinations, large portions of these documents are also redacted, making any informed review of their contents effectively impossible.

For these reasons, while our organizations have been able to comment on general legal and policy issues raised by the proposals, a broad spectrum of technical issues and their policy implications cannot be identified and meaningfully addressed because critical information is simply unavailable.

TSCA section 14(d)(7) authorizes EPA to disclose CBI “in any proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding.” EPA should invoke this provision to make CBI on the 13 chemicals available to interested parties desiring to conduct an in-depth review of the basis for the SNUR proposals, subject to appropriate safeguards to avoid broader dissemination of the CBI. At the same time, it should assure that the need for CBI treatment has been properly substantiated in accordance with section 14(c)(3) and that EPA has reviewed the validity of the CBI claims as required in section 14(g)(1).<sup>10</sup> After it completes this CBI review and supplements the record, EPA should extend the comment period so that interested parties can review the expanded record and present their views to the Agency. Without access to CBI and an opportunity to comment on it, final SNURs would violate the notice and comment requirements of the Administrative Procedures Act.

In conclusion, we believe the proposed SNURs are based on legally and scientifically flawed determinations that the SNUR chemicals are “unlikely to present an unreasonable risk of injury” under section 5(a)(3)(C) of TSCA. The law instead requires EPA to restrict these chemicals under section 5(e) orders. Thus, EPA should withdraw its determinations and proposed SNURs and replace them with section 5(e) orders and new SNURs codifying the requirements of those orders under section 5(f)(4). The failure of the proposed SNURs to assure protection of health and the environment against significant risks identified in EPA’s “not likely” determinations only serves to underscore their fundamental inadequacies under TSCA. EPA must also extend the comment deadline for the proposed SNURs and make essential CBI available to interested parties under appropriate safeguards so they can review this information and address it in their comments.

We appreciate the opportunity to offer these comments on the proposed SNURs.

If you have any questions, please contact SCHF counsel Bob Sussman at [bobssman1@comcast.net](mailto:bobssman1@comcast.net).

Respectfully submitted,

Liz Hitchcock  
Acting Director  
Safer Chemicals, Healthy Families

Daniel Rosenberg  
Senior Attorney  
Natural Resources Defense Council

---

<sup>10</sup> The extensiveness of the redacted CBI and the many types of information it includes raise concern about the validity of the submitters’ CBI claims and call into question whether the Agency has assured that they have been properly substantiated and conducted a review of their legal sufficiency under established standards for protecting trade secrets and competitively sensitive information. There is nothing in the record to document that adequate substantiation was provided by the CBI claimants or that EPA examined the validity of their claims as required by section 14 of TSCA and weeded out claims lacking in merit.