Environmental Defense Fund Comments on
Significant New Use Rules on Certain Chemical Substances
EPA-HQ-OPPT-2017-0366
Submitted August 31, 2018

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on EPA's proposed rule covering 35 significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) applicable to 145 chemical substances. 83 Fed. Reg. 37455 (proposed Aug. 1, 2018). Premanufacture notices (PMNs) on each of the chemical substances were submitted to and reviewed by EPA, and all of the substances are subject to final TSCA § 5(e) consent orders. These comments are broadly applicable to all of the SNURs as proposed, in light of the policy change we identify below and the inconsistencies that we identify across the various proposed SNURs. Even though these comments are adverse, EDF supports EPA's promulgation of SNURs for all 145 chemical substances.

Contents:

I. EPA has instituted an *ad hoc* testing policy change without acknowledging it has done so and without meeting TSCA's requirements.

With these proposed SNURs, EPA has implemented a significant departure from past policy and practice by ceasing to include any testing requirements or identifying any recommended testing. Instead, each chemical-specific description in Unit IV of the direct final rule now only identifies "potentially useful information" that EPA indicates is only being "provided for informational purposes." 83 Fed. Reg. at 37717. Where an agency changes its prior 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's framing of such information needs is problematic for several reasons. First, in describing "potentially useful information" for each substance in Unit IV, EPA identifies particular hazard concerns, presumably based on specific potential effects identified in its PMN review and included in the corresponding consent order. For example, for PMN Numbers: P–14–0472 and P–14–0496, EPA's description in Unit IV is as follows:

> *Potentially useful information*: EPA has determined that certain information about the fate and human health toxicity of the PMN substances may be potentially useful to characterize the effects of the PMN substances in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. The submitter has agreed not to exceed the confidential production limit without performing a *skin sensitization study* and a *biodegradation test* on each substance. In addition, EPA has determined that the results of a *pulmonary effects* testing of the PMN substance may be potentially useful in characterizing the health effects of the PMN substances. Although the Order does not require this additional testing, the Order's restrictions on manufacture, processing, distribution in commerce, and disposal will remain in effect until the Order is modified or revoked by EPA based on submission of this or other information that EPA determines is relevant and needed to evaluate a modification request.

83 Fed. Reg. at 37704 (emphases added). This language strongly suggests EPA has already identified the information as not just potentially useful, but *actually* useful to its review of the PMN substance. Indeed, as EPA has specified the information through inclusion of a triggered testing requirement in the consent orders, it appears EPA has already deemed the information to be *necessary* for EPA to be able to conduct a reasoned evaluation of the PMN substance under

specified conditions.[1] Such information almost certainly remains useful in the evaluation of a SNUN submitted to EPA subsequently.

Yet in its new approach reflected in these chemical-specific descriptions, EPA has not defined what it means for information to be only potentially useful and why EPA does not identify the information as actually useful or necessary. Moreover, EPA provides no explanation for why it no longer identifies testing as "recommended testing," as it previously did, and instead only describes the associated information as "potentially useful." Failing to acknowledge, much less explain, a shift in policy is arbitrary and capricious. *See Fox TV Stations*, 556 U.S. at 515 ("To be sure, the requirement that an agency provide reasoned explanation for its action would ordinarily demand that it display awareness that it is changing position.").

Elsewhere in the proposed rule, EPA hints at what it has in mind:

> Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. *EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN.* EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing.

83 Fed. Reg. at 37703 (emphasis added). Is EPA seeking to institute through these proposed SNURs a new testing policy that is based on exposure considerations, along the lines of that called for under TSCA section 26(l)(3)? That provision reads as follows:

> (3) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—The policies, procedures, and guidance developed under paragraph (1) applicable to testing chemical substances and mixtures shall—

[1] More specifically, the Consent Order prohibits the PMN submitter from manufacturing the chemical substances beyond an aggregate production limit unless the PMN submitter provides EPA with a Local Lymph Node Assay and a Ready Biodegradation study. Consent Order for Premanufacture Notices (PMN) P14-0472 and P14-0496 (Sanitized) at 5-6, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0005. The Consent Order also states that an inhalation toxicity study "*would be required*" to evaluate certain effects "which may be caused by the PMN substances." *Id.* at x.

> (A) address how and when the exposure level or exposure potential of a chemical substance or mixture would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and (B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this title, including information relating to potentially exposed or susceptible populations.

15 U.S.C. § 2625(l)(3). We are not aware of any other effort to date by EPA to articulate the policy called for under this provision of TSCA, and indeed the deadline for having done so has passed. *See id.* § 2625(l)(1). Moreover, if EPA is seeking to do so now, in this *ad hoc* manner, its effort falls far short of TSCA's duty in section 26(l)(3) that requires EPA to articulate a policy that specifies *how* exposure will factor into testing decisions, *id.* § 2625(l)(3)(A), as well as how it will determine that additional information relating to potentially exposed or susceptible populations is needed, *id.* § 2625(l)(3)(B)). EPA's brief explanation of "potentially useful information" in unit IV of the proposed rule fails to meet either of these requirements.

If EPA's intent is to depart from prior policy and practice and institute a new exposure-based policy regarding testing, it must do so explicitly, and not in this limited context, with such cursory articulation of the policy, and in the absence of a request for public comment on the proposed changes.

Whatever EPA's intent, EPA has effectively sought to change policy in a decidedly one-directional manner.

First, EPA seems intent in the proposed SNURs on establishing that context-specific exposure considerations will drive all decisions about whether and when to require any testing for hazards. Yet TSCA section 26(k) requires EPA to take into consideration all "reasonably available" information, including both "hazard and exposure information." 15 U.S.C. § 2625(k). In its final risk evaluation rule, 82 Fed. Reg. 33726 (Jul. 20, 2017), EPA defined "reasonably available information" to include information EPA could reasonably obtain, including through requiring testing. *Id.* at 33748 (codified at 40 C.F.R. § 702.33).

Deciding whether a particular actual or potential level of exposure to a chemical substance is or is not significant requires knowledge of the associated hazard. Even a "low" exposure to a highly toxic substance may well present significant risk.

Second, EPA's description of what it has considered in making "any recommendation for information" includes various factors in TSCA that would tend to limit testing:

> Any recommendation for information identified by EPA was made based on EPA's *consideration of available screening-level data*, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made *after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models*. EPA also recognizes that whether testing/further information is needed will depend on the *specific exposure and use scenario* in the SNUN.

83 Fed. Reg. at 37703 (emphases added). EPA conspicuously omits, however, mention of numerous other factors included in TSCA that would tend to increase the need for information or testing. These include the need to ensure EPA has sufficient information to conduct a reasoned evaluation of a new chemical substance, 15 U.S.C. § 2604(a)(3)(B)(i); the need throughout the statute to identify, evaluate and protect against risks to potentially exposed or susceptible subpopulations, *see id.* § 2604(a)(3); the need to ensure that alternatives to vertebrate testing "provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment," *id.* § 2603(h)(2)(A); and the requirements that EPA base its decisions under section 5 on the "best available science," *id.* § 2625(h), on the weight of the scientific evidence, *id.* § 2625(*i*), and on all reasonably available information, *id.* § 2625(k).

EPA should refrain from seeking to implement an *ad hoc* testing policy through the issuance of individual SNURs, and if it pursues development of such a policy, it needs to articulate a clear and transparent proposal that addresses and balances all of the relevant factors in TSCA. When EPA develops the policy(ies) required by TSCA § 26(l)(3), EPA should provide the public with an opportunity to comment on a proposed draft(s) of the policy(ies).

II. The restrictions in SNURs must mirror the restrictions in § 5(e) and § 5(f) actions and orders.

A. The Lautenberg Act requires consistency between SNURs and § 5(e) and § 5(f) actions and orders.

When EPA issues a rule or order under TSCA § 5(e) or § 5(f), TSCA requires EPA to consider whether to promulgate a SNUR. 15 U.S.C. § 2604(f)(4). More specifically, EPA must either initiate a rulemaking or provide a statement explaining why EPA is not doing so. *Id.* When EPA promulgates such a SNUR, the SNUR must "identif[y] as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that *does not conform to the restrictions imposed by the action or order*" under TSCA § 5(e) or § 5(f). *Id.* (emphasis added). The statute's plain language requires a SNUR to impose restrictions that "conform" to the restrictions in a § 5(e) or 5(f) order or a § 5(f) rule. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002) (statutory interpretation "begin[s] with

the language of the statute"). As relevant here, "conform" means to "comply with rules, standards, or laws." *Oxford English Dictionary* 365 (3d. ed. 2010). Therefore, in implementing this provision, EPA is to promulgate SNURs that identify as a significant new use any action that does not comply with the restrictions in the corresponding § 5(e) and § 5(f) actions or orders.

B. EPA should not deviate from prior policy and practice, which correctly implements the law.

Since the Lautenberg Act passed, EPA has consistently required SNURs to conform to the restrictions in corresponding section 5(e) orders. In fact, every direct final rule promulgating SNURs published since the Lautenberg Act passed, until this one, has included the following language in the preamble:

> Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The SNURs are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The SNURs designate as a "significant new use" *the absence of the protective measures required in the corresponding consent orders*.[2]

Moreover, in June 8, 2017, EPA withdrew a direct final SNUR and proposed it in modified form in response to public comment, in order to make the SNUR "consistent" with the consent order requirements. 82 Fed. Reg. 26644, 26645 (June 8, 2017).

Additionally, even before the Lautenberg Act introduced this new provision, EPA's policy has been for SNURs to be consistent with section 5(e) orders. For instance, the 1989 regulation establishing much of the SNUR procedures stated that "the standard SNUR language is designed to track the corresponding section 5(e) order provisions." 54 Fed. Reg. 31298, 31299 (Jul. 27, 1989). As an example, in a SNUR from 2003, EPA stated that "the SNUR provisions for these chemical substances listed in this document are *consistent with* the provisions of the TSCA section 5(e) consent orders." 68 Fed. Reg. 70155, 70171 (Dec. 17, 2003) (emphasis added).

The current direct final rule conspicuously omits the earlier, consistently used language, "[t]he TSCA section 5(e) SNURs designate as a 'significant new use' *the absence of the protective measures required in the corresponding consent orders*."[3] Instead, it lists for each chemical substance certain conditions (that are not always consistent with the consent order), and then states only that "[t]he SNUR will designate as a 'significant new use' the absence of these

[2] *See* 82 Fed. Reg. 48637, 48639 (Oct. 19, 2017) (emphasis added); *see also* 82 Fed. Reg. 44079, 44080 (Sept. 21, 2017); 81 Fed. Reg. 81250, 81251 (Nov. 17, 2016).
[3] *Supra* note 2.

protective measures ***," 83 Fed. Reg. 37702, 37704 (Aug. 1, 2018), with no immediate reference to the corresponding consent order.

EPA should not deviate from this longstanding policy, now codified into TSCA. And it should certainly not do so without explaining and subjecting to public notice and comment its policy rationale and legal basis for doing so.

III. The proposed SNURs are not consistent with the associated consent orders.

In the proposed rule, EPA has specified language for 35 SNURs covering 145 chemical substances, the PMNs for which are subject to 25 corresponding section 5(e) consent orders. EPA provided 30 days to comment on the proposal, which has a docket of over 300 supporting documents. Despite the short timeframe and large size of the docket, EDF has done its best to identify inconsistencies between the proposed SNURs and the corresponding consent orders – but the limited time means we may well not have identified all the inconsistencies. In promulgating the final SNURs EPA must eliminate the inconsistencies we have identified by making each SNUR conform to the corresponding section 5(e) order. EPA should also ensure that there are no other inconsistencies between the consent orders and the corresponding final SNURs.

Protection in the Workplace:

A number of the proposed SNURs identify a significant new use as any use where worker protection equipment is not provided. Some but not all of the SNURs correctly mirror the corresponding consent order by requiring specific respirators, gloves, and other equipment to be used when the chemical is present in a specified "form" or physical state. *See, e.g.*, 83 Fed. Reg. at 37727 (to be codified at 40 C.F.R. § 721.11045(a)(2)(i)) (citing 40 C.F.R. § 721.63(a)(6)). In this case, the SNUR mirrors the corresponding consent order. *See* Sanitized Consent Order P16-0495 at 12, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0081.

Notably, these restrictions are not included directly in the proposed SNURs themselves. Rather, the restrictions in the proposed SNURs are incorporated by reference to requirements in EPA's general regulations. For workplace protections, the proposed SNURs cite "the requirements" in 40 C.F.R. § 721.63, which states that a significant new use is any use where a company has not established a program in which:

> [e]ach person who is reasonably likely to be dermally exposed in the work area to the chemical substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in the form *listed in paragraph (a)(6) of this section*,

> and *cited in subpart E* of this part for the chemical substance, is provided with, and is required to wear, personal protective equipment ***.

40 C.F.R. § 721.63(a)(1) (emphases added); *see also* 40 C.F.R. § 721.63(a)(4) (workplace protections against inhalation of a chemical substance contains the same italicized language). In turn, "paragraph (a)(6)" states that:

> [w]hen *cited in subpart E* of this part for a substance, the following airborne form(s) of the substance apply to paragraphs (a)(1) and (4) of this section.

40 C.F.R. § 721.63(a)(6) (emphasis added). Thus, EPA's general regulations are written with the expectation that the forms of the substance that can become airborne and will necessitate workplace protections must be spelled out in the SNUR itself (i.e., in subpart E).

The consent orders correctly follow this approach. For instance, the Consent Order for P-16-0495 states that:

> the Company must establish a program whereby *** [e]ngineering control measures *** or administrative control measures *** shall be considered and implemented to prevent exposure, where feasible to each person who is reasonably likely to be dermally exposed in the work area to the PMN substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne *in a form listed in subparagraph (a)(3) of this section*.[4]

Subparagraph (a)(3) of that section of the Consent Order then states that:

> The following physical states of airborne chemical substances are listed for subparagraph (a)(l) of this section:
>
> (i) Particulate (including solids or liquid droplets).[5]

In other words, when the chemical is present as a particulate in the air, workplace protection against dermal exposure is required by the consent order. In this case, the proposed SNUR for P-16-0495 correctly mirrors this language. The proposed SNUR states that a significant new use is:

---

[4] Sanitized Consent Order P16-0495 at § (a)(1), 11, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0081 (emphasis added).
[5] *Id.* at § (a)(3), 12.

> [r]equirements as specified in *§ 721.63(a)(1)*, (3), when determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering controls measures *** or administrative control measures *** shall be considered and implemented to prevent exposure, where feasible, *(a)(6) (particulate)*, (b) (concentrations set at 1.0%), and (c).

83 Fed. Reg. at 37727 (to be codified at 40 C.F.R. § 721.11045(a)(2)(i)) (emphases added). The proposed SNUR identifies "(a)(6) (particulate)" as a form of the chemical substance which requires workplace protection under section (a)(1), mirroring the Consent Order.

A number of proposed SNURs do not identify the same forms as the corresponding consent orders, however, and a few do not list any of the forms identified in the consent order, despite relying on the workplace protections in 40 C.F.R. § 721.63(a)(1) and (4). For instance, the Consent Order for P-17-0272 identified three forms:

> [t]he following physical states of airborne chemical substances are listed for subparagraphs (a)(1) of this section:
> (i) Particulate (including solids or liquid droplets),
> (ii) Gas/vapor (all substances in the gas form), or
> (iii) Combination Gas/vapor and Particulate (gas and liquid/solid physical states are present; a good example is paint spray mist, which contains both liquid droplets and vapor).[6]

The corresponding proposed SNUR does not identify any forms, and has no cross-reference to subparagraph (a)(6). Rather, it only states that:

> [r]equirements as specified in § 721.63(a)(1), (a)(2)(i), (iii), (iv), (a)(3). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1) engineering control measures *** or administrative control measures *** shall be considered and implemented to prevent exposure, where feasible.

83 Fed. Reg. at 37733 (to be codified at 40 C.F.R. § 721.11057(a)(2)(i)). This inconsistency is significant because if the form of the chemical substance is not identified in subpart E (i.e., in the proposed SNUR), the workplace protections required under § 721.62(a)(1) or (a)(4) will not fully apply for the dermal and airborne exposures to those forms. *See* 40 C.F.R. § 721.62(a)(1), (4).

[6] P17-0272 to 0277 Signed Consent Order Sanitized at 10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0332.

Below are PMNs where one, or all, of the forms identified in the corresponding consent order are not specified in the proposed SNURs:[7]

- Does not identify *any* of the forms identified in the consent order: P-14-0472, P-14-0496, P-16-0358, P-17-0272-77, P-17-0278-80
- Does not identify particulate form: P-15-0707, P-16-0430, P-16-0513
- Does not identify gas/vapor form: P-16-0399
- Does not identify combination of gas/vapor and particulate (EPA provides as an example in the consent order, "paint spray mist"): P-14-0630, P-15-0450, P-15-0705-07, P-16-0322, P-16-0352 (chemicals A and B), P-16-0399, P-16-0430, P-16-0513, P-17-0032, P-17-0033-140

EPA must eliminate these inconsistencies in the final SNURs and ensure that all forms triggering worker protections specified in the consent orders are also specified in the corresponding final SNURs.

Industrial, Commercial, and Consumer Activities:

The proposed SNURs also typically include some restrictions on industrial, commercial, and consumer activities. These may include use restrictions, volume limitations, or process limitations. There were numerous instances, however, where the SNURs deviated from such restrictions specified in the consent orders.

First, a number of the consent orders require the manufacturing volume (including import) to cease after a period of time unless certain conditions have been met. For instance, some consent orders set a time limit that triggers testing requirements, effective from the Notice of Commencement date, after which the chemical substance can no longer be manufactured by the company subject to the consent order unless the testing is conducted. *See, e.g.*, Consent Order P15-0450 at 5, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0016. Other consent orders set a volume limit that cannot be exceeded unless the testing is conducted.

Such time limits and volume limits need to be incorporated into the proposed SNURs.

[7] For one proposed SNUR, P-17-0198, there is no inconsistency with the Consent Order because neither identifies any forms. However, the Consent Order itself appears to contain an error because it says dermal protection is required if "the substance becomes airborne in a form listed in subparagraph (a)(4) of this section," but then it does not have a section (a)(4), nor does it identify any forms in any other section. *See* Sanitized Consent Order P17-0198 at 7-9, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0208.

As proposed, the SNURs appear to rely on 40 C.F.R. § 721.80(p) to effectuate this type of restriction in the consent orders.[8] 40 C.F.R. § 721.80(p) states that, where a substance is specified as being subject to that section, a significant new use is the "[a]ggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance," in the proposed SNURs. 40 C.F.R. § 721.80(p). This delineation of a significant new use clearly only includes a *volume* limitation. In prior SNURs codified in subpart E, EPA cites to 40 C.F.R. § 721.80(p) and correctly specifies a volume limitation. *See, e.g.*, 40 C.F.R. §§ 721.10524, 721.10935.

EPA's reliance only on cross-referencing 40 C.F.R. § 721.80(p) is problematic because in a number of the proposed SNURs (listed in fn. 8) EPA cites 40 C.F.R. § 721.80(p) as identifying a significant new use but then only specifies a *time* limitation (e.g., 6 months, 12 months, 6 years), not a *volume* limitation. Including only a time limitation in the SNURs in subpart E while also citing § 721.80(p) – which provides only for a volume limitation – creates confusion regarding the actual restriction applicable to the substance. If EPA's intention is to impose a volume limitation, EPA should clearly identify the specific volume in the proposed SNUR. And if EPA wants to set a time limitation instead of or in addition to a volume limitation, EPA must spell that out in the proposed SNUR. For instance, in the past, EPA has set a limit at "any amount after [x date]." *See, e.g.*, 40 C.F.R. §§ 721.10522, 721.10527, 721.10619. Regardless of the approach, EPA must ensure that the final SNURs capture all of the restrictions in the consent orders.

EPA's approach to specifying time limitations is made even more confusing because the proposed SNURs fail to explain that the time limit originated and is specified in the consent order, and more importantly fail to identify the trigger that starts the clock ticking toward the time limit. The proposed SNURs state that a significant new use is any use as described in 40 C.F.R. § 721.80(p), with a time period (e.g., six months) noted in parentheses but without any further explanation. While the original PMN submitter may understand this in the context of its consent order, any other company subject to the SNUR would not. EPA needs to specify, at a minimum, when the time period commences, which based on the consent order is upon the PMN submitter's filing of a notice of commencement (NOC). Even then, it is not clear how a second company would timely know that a NOC had been filed by the PMN submitter, thereby triggering the time period to start. It is also not clear how EPA would address a situation in which a SNUR is finalized preceding or otherwise in the absence of the filing of a NOC.

Second, the Consent Order for P-16-0289 includes numerous time limitations on the manufacturing volume of the chemical substance, yet the corresponding proposed SNUR fails to include all but one of them. The proposed SNUR states that a significant new use is any use as

[8] The proposed SNURs covering the substances in P-15-0450, P-16-0289, P-16-0399, and P-17-0198 each propose to rely on this restriction for a time limitation. 83 Fed. Reg. at 37721, 37723, 37724, and 37732. See below for additional concerns relating to P-16-0289.

described in 40 C.F.R. § 721.80(p), with "six months" in parentheses. In addition to the concern raised previously about the ambiguity of relying solely on a time limitation when EPA also intends to have a volume limitation, in this case the Consent Order sets additional limitations *that are not included at all in the SNUR*. These include a prohibition on manufacturing unless the company "measures the particle size distribution to characterize the particle size distribution of fractions less than 10 microns of the dry particle PMN substance": (1) twice every twelve months *after* the six months is over, if there is commercial production, until a total of six tests are performed; and (2) if there are changes in the manufacturing process that could result in different particle sizes. Sanitized Consent Order P16-0289 at p. 5-6, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0038.

Rather than rely solely on cross-referencing 40 C.F.R. § 721.80(p), EPA should spell out the restrictions from the Consent Order in the proposed SNUR or cite to 40 C.F.R. § 721.80(k) and (q), which in turn cite to the restrictions set by the Consent Order. (Of course, for this to be viable, the consent order itself would need to be made readily and timely available.) Ultimately, whichever way EPA chooses to make this correction, EPA must make sure that the limits set by the final SNUR are clear, and fully conform to the limits in the Consent Order.

Lastly, there are numerous additional discrepancies between consent orders and their corresponding proposed SNURs with respect to the specification of significant new uses for industrial, commercial, and consumer activities. For instance:

- For P-14-0630, the Consent Order states that using the chemical in a consumer product that generates "vapor" is prohibited. Consent Order P14-0630 (Sanitized) at 48, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0012. The SNUR does not include generation of vapor as a significant new use. 83 C.F.R. at 37721.

- For P-16-0273-74, the Consent Order states that the chemical substance can only be imported in totes. Consent Order P16-0273 and P16-0274 (Sanitized) at iv, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0034. The SNUR does not include that limitation. 83 C.F.R. at 37723.

- For P-16-0495, the Consent Order states that the PMN substance can only be used for a specific use (which is redacted as confidential business information (CBI)). Sanitized Order P16-0495 at p. 23, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0081. The SNUR sets no such limit. 83 Fed. Reg. at 37727. The SNUR should cite to 40 C.F.R. § 721.80(k) ("use other than allowed by the section 5(e) consent order").

- For P-17-0032, the Consent Order includes a separate volume limit for *processing* the substance. Consent Order for P17-0032 (Sanitized) at p. iv, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0125. The SNUR only sets a volume limit for manufacture and import and not one for processing. 83 Fed. Reg. at 37729. EPA must include the processing limit in the SNUR.

Human Health, Environmental Hazard, Exposure, and Precautionary Statements:

The proposed SNURs also include requirements for hazard communication. These include "Human Health, Environmental Hazard, Exposure, and Precautionary" statements that must appear on any label or safety data sheet required by the SNUR. There are some inconsistencies between the statements required by the SNURs and those required in the corresponding consent orders.

- For P-14-0496, the SNUR is missing the "disposal restrictions apply" warning specified at 40 C.F.R. § 721.72(g)(4)(i). This warning is required by Consent Order for Premanufacture Notices (PMN) P14-0472 and P14-0496 (Sanitized) at 21, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0005.

- For P-17-0272, the SNUR is missing the precautionary statement for developmental effects (40 C.F.R. § 721.72(g)(1)(vi)). This statement is required by P17-0272 to 0277 Signed Consent Order Sanitized at 19, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0332.

Given that each of these precautionary statements is required by the corresponding consent orders, they must be included in the final SNURs.

Additionally, for two of the proposed SNURs associated with the Consent Order for P-17-0033-140, the proposed SNURs are lacking a requirement for three hazards statements: toxic to fish (40 C.F.R. § 721.72(g)(3)(i)), toxic to aquatic organisms (40 C.F.R. § 721.72(g)(3)(ii)), and disposal restrictions apply (40 C.F.R. § 721.72(g)(4)(i)). The two SNURs are for certain halogenated sodium benzoate salts, 40 C.F.R. § 721.11053, and certain halogenated sodium benzoic acids, 40 C.F.R. § 721.11054. Because the Consent Order applies to multiple substances and redacts certain information (likely health and safety information not eligible for redaction under TSCA § 14), it is not possible for the public to know whether the hazard statements are or are not required for the chemicals subject to the SNURs noted above. Consent Order for Premanufacture Notice (PMN) P17-0033 Sanitized at p. 47, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0344. EPA should ensure that there are no inconsistencies between the requirements of the SNURs and the Consent Order for these chemicals.

IV. EPA must address additional errors in the proposed SNURs.

For P-17-0033 through P-17-0140,[9] there are three separate SNURs that cover the many chemicals covered by that one Consent Order. Consent Order for Premanufacture Notice (PMN) P17-0033 Sanitized, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0344. The SNUR for sodium benzoate salts states that a significant new use is any use other than those allowed in the section 5(e) order, which is applicable to all of the substances P-17-0033 through P-17-0140. 83 Fed. Reg. at 37730 (to be codified at 40 C.F.R. § 721.11053(a)(2)(iii)) (citing 40 C.F.R. § 721.80(k)). This restriction is not specified in the other two SNURs. 83 Fed. Reg. at 37731-32 (to be codified at 40 C.F.R. §§ 721.11054(a)(2)(iii), 721.11055(a)(2)(iii)). EPA must fix this error and ensure that each proposed SNUR contains all of the restrictions governing the relevant chemicals that appear in the Consent Order.

Additionally, P-16-0352 had one Consent Order covering two separate chemicals, which each have a proposed SNUR. The volume limitation set in the Consent Order was for the substances combined. Sanitized Consent Order P16-0352 at 5-6, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0366-0057. Both proposed SNURs contain errors. First, the combined volume limits set in 721.11039 are incorrect because it cites itself twice – "this substance and the substance subject to 721.11039" – instead of citing itself and the other PMN substance at section 721.11040. 83 Fed. Reg. at 37725. Second, section 721.11040 cites to an incorrect SNUR, "§ 721.9998," for its combined volume limit, when it should cite to the other PMN substance at section 721.11039. *Id.* EPA must ensure that the combined volume limitations in the final SNURs are correct.

Conclusion

EPA has adopted an *ad hoc* testing policy in the direct final rule that does not comply with the requirements of TSCA, without sufficient explanation, and without providing any notice and opportunity for public comment on the policy. Additionally, the Lautenberg Act requires SNURs to conform to the restrictions in actions and orders under sections 5(e) and 5(f), and it is EPA's longstanding policy to ensure that SNURs are consistent with section 5(e) orders. Therefore, EPA must ensure that the final SNURs identify as a significant new use any activity that is not consistent with the restrictions in the corresponding section 5(e) consent orders.

* * * * *

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

[9] Although we refer to the full range of PMNs here for ease of citation, there are three PMNs that fall within this range that are covered by separate consent orders and are not covered by the proposed SNURs: P-17-0121, P-17-0116, and P-17-0049.