



Environmental Defense Fund
Request for an Extension of the Comment Period on
Modification of Significant New Use of a Certain Chemical Substance
EPA-HQ-OPPT-2011-0941
PMN P-03-325 & SNUN S-17-4
Submitted February 12, 2018

Director Jeffery Morris
Office of Pollution Prevention and Toxics
Via <http://www.regulations.gov> and electronic mail

Dear Director Morris:

EPA is proposing to amend the significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for Oxazolidine, 3,3'-methylenebis[5- methyl-, which was the subject of a premanufacture notice (PMN) and one or more significant new use notices (SNUNs).¹ 83 Fed. Reg. 5598 (Feb. 8, 2018). This action would amend the SNUR to allow certain new uses reported in the SNUNs without requiring notification. *Id.* EPA has stated that any comments on the proposed amendment to the SNUR must be received by February 23, 2018. *Id.*

On behalf of our members, supporters, and organization, the Environmental Defense Fund (EDF) makes three related requests regarding this proposed rule.

1. Please provide at least 30 days for public comment after the complete public files are available: EDF requests that EPA extend the public comment period to provide at least 30 days for interested persons to provide comments on the proposed amendment to the SNUR, to commence *after* EPA has provided the complete public file for the proposal. Thus, if EPA provided the complete public file today, comments would be due on March 14, 2018.

2. Please disclose all relevant information that does not meet all of the requirements for nondisclosure under TSCA § 14: EDF also requests that the agency

¹ As explained below, it is unclear from the current record whether EPA received one or more SNUNs for this chemical substance. EPA has provided a single SNUN case number, but based on other documents in the docket, there appear to be two SNUNs or two versions of the SNUN. Absent evidence to the contrary, we assume there were multiple SNUNs in light of the references to multiple submission dates in the docket.

publicly disclose *all* non-confidential information from the file or files for both the premanufacture notice (PMN) and significant new use notices (SNUNs) for Oxazolidine, 3,3'-methylenebis[5-methyl-. EPA's regulations require that these materials be electronically available, and as explained below, EPA has already violated those regulations by failing to make them available earlier, including electronically. *See, e.g.*, 40 C.F.R. §§ 720.95, 700.17(b)(1), 720.80(b)(2)(ii). Indeed, even now the SNUNs for this chemical substance are not in the electronic docket on regulations.gov, nor is all of the supporting documentation.

In addition, when making these materials available electronically, EPA must ensure that it fully discloses information as required by TSCA § 14, particularly health and safety studies and health and safety data—whether submitted by the PMN or SNUN submitters or developed by EPA in its review of the PMN and SNUNs. EPA must review confidentiality claims asserted by the PMN or SNUN submitters and deny any claims for nondisclosure that do not meet the stringent requirements of TSCA § 14. EPA must also ensure that any redactions it includes in the materials or its own review documents meet all of the requirements of TSCA § 14. Until the information is disclosed, the public is prejudiced in its efforts to comment on this proposed amendment to the SNUR. EPA should release this information expeditiously and should not commence the comment period until all of the information is readily electronically available to the public.

3. Please respond to this request within three business days: EDF also requests that EPA respond to this extension request within three business days since, if the extension were denied, we would only have eight days to prepare a response.

An extension is required for three major reasons. *First*, the short comment period is itself contrary to law and arbitrary and capricious, and it seriously prejudices the public's, including EDF's, ability to comment on the proposed rule. *Second*, EPA has already committed a number of procedural violations in its review of the SNUNs leading to the proposal of this amendment to the SNUR. Those violations render the amendment to this SNUR and any other decisions resulting from the review of these SNUNs legally vulnerable. EPA must cure those violations and then allow adequate time for public comment. *Third*, this proposed amendment to the SNUR allows a new use of the chemical substance—as an anti-corrosive agent in oilfield operations and hydraulic fluids—despite numerous hazards presented by the chemical substance. In such circumstances, EPA must follow the law and provide the public adequate time to review and comment on the proposal.

I. The timeline for consideration of the amendment to the SNUR is unlawful and unreasonable.

The Administrative Procedure Act (APA) requires EPA to “give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.” 5 U.S.C. § 553(c). “[A] thirty-day period is, in the Administrative Conference’s view, ‘an inadequate time to allow people to respond to proposals that are *complex or based on scientific or technical data.*’ The Administrative Conference itself thus suggests a sixty-day period as ‘a more reasonable minimum time for comment.’” *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984) (emphasis added). The amendment to the SNUR for this chemical substance constitutes a proposal that is complex and based on scientific and technical data, and

thus a 30-day period is arguably inadequate. A 15-day period is even more unreasonable than a 30-day period.

EPA's regulations provide two mechanisms for expedited promulgation of SNURs. *See* 40 C.F.R. §§ 721.160, 721.170. At a bare minimum, EPA must provide as much opportunity for public comment as it does under its expedited procedures. Here, EPA issued a § 5(e) order governing the activities identified in the SNUNs "based on a determination that the substance may present an unreasonable risk of injury to human health and the environment." 83 Fed. Reg. at 5600. Thus, the provisions of § 721.160 would govern the promulgation or amendment of the SNUR at issue. *See* 40 C.F.R. § 721.160(a). When EPA promulgates a SNUR through notice and comment procedures after a § 5(e) order (as here):

When EPA uses a notice and comment procedure to issue a significant new use rule, EPA will issue a proposal in the FEDERAL REGISTER following its decision to develop a significant new use rule under this section for a specific new chemical substance. *Persons will be given 30 days to comment* on whether EPA should establish notification requirements for the substance under this part.

40 C.F.R. § 721.160(c)(4)(i) (emphasis added). In practice, EPA has afforded at least 30 days for interested persons to provide comments, or notice of intent to submit adverse or critical comments, on SNURs. *See, e.g.*, 82 Fed. Reg. 26,644 (June 8, 2017) (providing 32 days to comment on proposed rule); 82 Fed. Reg. 48,637 (Oct. 19, 2017) (providing 32 days to submit notice of intent to submit adverse comments on direct final rule); 82 Fed. Reg. 44,079 (Sept. 21, 2017) (providing 32 days to submit notice of intent to submit adverse comments on direct final rule). Thus, as a matter of law, EPA must provide interested persons with a minimum of 30 days to submit comments.

EPA should fix its current procedural violation by providing the amount of time required by its regulations. At an absolute minimum, EPA should provide the public with 30 days to comment on the proposed amendment to the SNUR.

Moreover, it would be arbitrary and capricious for EPA to deny EDF's requested extension given EPA's precedent of granting many extensions at industry request. EPA has regularly granted extensions for comment periods on other aspects of TSCA's implementation, with such requests overwhelmingly being made by industry representatives, even when the original deadlines provided much more than 15 days. For example, EPA granted industry requested extensions on CDR reporting, on the three rulemakings arising from pre-Lautenberg risk assessments (involving TCE, DCM, and NMP), and the mercury inventory rule. Particularly relevant here, EPA has also granted lengthy extensions to comment on SNURs at industry request. For example, on October 27, 2016, EPA proposed SNURs for three chemicals and initially requested comments by November 28, 2016. 81 Fed. Reg. 74,755 (Oct. 27, 2016). The American Chemistry Council (ACC) requested a 60-day extension, and EPA reopened the comment period and allowed comments until March 6, 2017—ultimately providing ACC approximately 130 days to comment on those SNURs. *See* 82 Fed. Reg. 80 (Jan. 3, 2017); *see also* <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0810-0246>. For EPA to deny an extension to EDF here would be fundamentally arbitrary and capricious.

II. EPA has already committed procedural violations by failing to make the relevant public file available earlier; EPA must cure those violations and ensure that interested persons have at least 30 days to comment on the *full* record.

Under TSCA § 5(d), each PMN and SNUN “shall be made available, subject to section 14, for examination by interested persons.” 15 U.S.C. § 2604(d). EPA must process SNUNs “in accordance with the procedures of [40 C.F.R. Part 720]” (which govern PMNs) and persons submitting SNUNs must follow those regulations as well. 40 C.F.R. § 721.25(c); *see also* 40 C.F.R. §§ 721.25(a), 721.5(a), 721.1. Thus, EPA must follow the procedures that govern its review of PMNs when reviewing a SNUN.

EPA’s implementing regulations provide that “[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the *public file* for that notice.” 40 C.F.R. § 720.95 (emphasis added). Those “[p]ublicly available docket materials are available at the address[] in § 700.17(b)(1).” *Id.* Section 700.17(b)(1) states that “[p]ublicly available docket materials are available in the electronic docket at <http://www.regulations.gov>.” *Id.* § 700.17(b)(1). Thus, the public files must be publicly available in electronic dockets at [regulations.gov](http://www.regulations.gov).²

EPA’s regulations also require that SNUN submitters, if they claim information in either the SNUN or attachments is confidential, “must also provide EPA with a sanitized copy.” 40 C.F.R. §§ 720.40(d)(2), 720.80(b)(2). Indeed, “the notice review period will not begin until EPA receives the sanitized copy.” 40 C.F.R. §§ 720.80(b)(2)(iii), 720.65(b)(vii) (“[T]he notification period does not begin if *** the submitter does not submit a second copy of the submission with all confidential information deleted for the public file.”). “EPA *will* place [the] sanitized copy in the public file.” *Id.* § 720.80(b)(2)(ii) (emphasis added). Therefore, EPA should not have even begun to review the SNUNs until EPA had received sanitized copies of all materials for public release, and EPA then should have placed those sanitized copies in the public files.

EPA has violated its own procedural regulations by failing to place those sanitized public copies of the SNUNs and the supporting documents in the mandatory, electronic public files upon receipt. If EPA had complied with its regulations, then the public would have been able to review the SNUNs and supporting documentation shortly after their submission. EDF would have then had at least nine months to review the SNUN, S-17-4. *See* 83 Fed. Reg. at 5600 (stating that EPA received the SNUN on April 12, 2017). Given that it took EPA over nine months to review the SNUNs, it is absurd for EPA to give the public a mere 15 days both to review the public files and to draft comments on them.

Indeed, as of now, numerous relevant documents *still* do not appear in the public file, and the docket for the amendment to the SNUR is woefully incomplete:

² EDF previously drew EPA’s and the public’s attention to these general regulatory violations in our questions submitted on November 20, 2017, more than 80 days ago. EDF Questions for Public Meeting on Implementing Changes to the New Chemicals Review Program under Amended TSCA, pp.4-5, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0014>. EPA should address those regulatory violations.

A. **EPA must add the SNUNs to the docket.** No SNUN appears in the docket. *See* <https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2011-0941>. Based on other documents in the docket, there appear to be two SNUNs or two versions of the SNUN. The consent order indicates that the SNUN was received on January 13, 2017. Consent Order at p.iii. In contrast, the proposed amendment to the SNUR indicates that the SNUN was received on April 12, 2017. 83 Fed. Reg. at 5600. Both SNUNs or versions of the SNUN need to be added to the docket.

B. **EPA must include all documents attached to the SNUNs or accompanying the SNUNs.** Presumably the SNUNs included or referred to attachments or other accompanying or associated documents. EPA's regulations make it clear that "all information" accompanying a SNUN, "including any health and safety study and other supporting documentation," should become part of the public file. 40 C.F.R. § 720.95. EPA needs to add all of these documents to the docket, redacted only as permitted under TSCA § 14, as amended by the Lautenberg Act.

C. **All the other relevant documents need to be added to the docket, particularly health and safety studies.** The consent order refers to various documents that do not appear to be in the docket, including some documents that are clearly health and safety studies. For example, the order refers to an acute inhalation study (OECD 436) and monitoring studies of formaldehyde release in specific industrial settings. Consent Order at p. v. These studies, including underlying information, are directly relevant to the basis for EPA's proposed amendment of the SNUR, and they must be included in the docket. Similarly, the engineering report refers to various documents that do not appear to be in the docket. For example, the report repeatedly refers to various supplemental documents provided by the submitter. EPA considered these documents during its analysis and they are part of the administrative record. They too must be included in the docket.

D. **The complete record from the PMN should be in the docket.** A redacted version of the original PMN (P-03-0325) is included in the docket and has a long list of attachments. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0941-0134>. It includes about 550 pages of attachments, but the list indicates that the attachments consist of 1,000 pages, so a significant fraction appear to be missing. PMN at 12-12a. Among the missing attachments are one or more Safety Data Sheets (SDS) and at least portions of health and safety studies (*e.g.*, only the first 21 out of 421 pages of a 90-day repeat dose oral toxicity study are attached to the PMN).

EDF does not know whether any of these documents are available through the docket center, but even assuming they are available there, from our experience it would take approximately two weeks—the full time EPA allotted for public comment—to receive the documents from the Docket Center. Moreover, the documents should be available for all members of the public who may wish to comment on this amendment to the SNUR. Thus, EPA must place these documents in the public docket so that all interested persons will have access to the relevant files.

In addition, EPA has an affirmative obligation to review at least 25% of non-chemical identity confidentiality claims under TSCA, 15 U.S.C. § 2613(g), and EPA has stated that it is implementing that obligation by "review[ing] every fourth submission received that contains non-chemical identity [confidential business information (CBI)] claims."

<https://www.epa.gov/tsca-cbi/epa-review-and-determination-cbi-claims-under-tsca> (last visited

Dec. 18, 2017). Most such claims are now required to be accompanied by substantiating information at the time they are asserted, *i.e.*, when the SNUNs were submitted. EPA must complete reviews of confidentiality claims within 90 days of receipt of the claims, and if EPA denies a claim, EPA must disclose the information that had been claimed confidential 30 days after notifying the claimant of the denial, absent a challenge to the denial in district court. 15 U.S.C. § 2613(g)(1)(A), (g)(2)(B). Since EPA received the SNUNs at issue over 120 days ago, EPA should have completed reviews of any confidentiality claims that were selected through EPA's review of every fourth submission. In those cases, EPA should have already placed, and certainly should now place both the original sanitized copy and a final, reviewed, and resanitized copy in the dockets, along with any documentation of EPA's "determinations" about those confidentiality claims.

In addition, when EPA adds the health and safety studies to the docket, EPA must ensure that it discloses information as required by TSCA § 14. TSCA requires disclosure of "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). Thus, any health and safety studies related to these chemicals must be disclosed. 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) (emphases added). TSCA defines "health and safety study" to mean "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. § 2602(8). EPA has provided further details on this expansive definition of "health and safety study," explaining that it encompasses, among other things, "[a]ny data that bear on the effects of a chemical substance on health or the environment" and "[a]ny assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance." 40 C.F.R. § 720.3(k). Thus, any health and safety study or other data on health or environmental effects or assessment of risk EPA prepared must be disclosed. The *only* exception from that disclosure requirement is for "information *** that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture." 15 U.S.C. § 2613(b)(2).

EPA should ensure that the public has at least 30 days to comment on the full record, *after* an adequate review and disposition of the confidentiality claims.

III. When EPA allows a significant new use of a hazardous chemical substance, EPA should not rush to judgment or deny the public an opportunity to meaningfully comment.

EPA's proposed rule would amend the relevant SNUR to allow certain new uses reported in the SNUNs to take place without requiring additional SNUNs. 83 Fed. Reg. at 5598. Under the new SNUR, this chemical substance could be used as an anti-corrosive agent in oilfield operations and hydraulic fluids without notification. *Id.* at 5600. EPA has identified a number of concerns about this chemical substance, including aquatic toxicity, systemic toxicity, severe skin and eye irritation, neurotoxicity, mutagenicity, oncogenicity, allergic responses, and

developmental toxicity. *Id.* at 5600. EPA also has identified concerns regarding the expected release of formaldehyde from the substance. *Id.* Given the numerous identified hazards from this substance, EPA must ensure that the amended SNUR defines significant new uses in a manner that protects human health and the environment. And EPA must provide the public with sufficient opportunity to thoroughly vet the proposed amendment to the SNUR.

Instead, EPA has given the public 15 days to review the proposed amendment based on an incomplete record. EPA has provided *no* rationale for such a short comment period, and such short comment periods usually require truly “exigent circumstances.” *See N.C. Growers’ Ass’n v. UFW*, 702 F.3d 755, 770 (4th Cir. 2012) (finding 10-day comment period violated the APA). EPA proposes to make the final rule effective 15 days after publication on theory that there is “good cause” for a quick effective period “because the rule largely relieves a restriction, and because the SNUR modification pertains only to new uses, there are no persons who need time to adjust existing operations.” 83 Fed. Reg. at 5599. EPA points to no precedent that these types of reasons provide “good cause” to shorten the comment period, and if anything, the circumstances cut in the opposite direction. EPA created the initial SNUR because this chemical substance poses hazards to human health and the environment, and the current information continues to confirm that the chemical substance presents hazards. In these circumstances, EPA should proceed cautiously and in full compliance with the law. EPA has no justification for rushing its decision-making here.

In light of the complex issues raised by the amendment to the SNUR, and the significant, deleterious impacts EPA’s proposed actions could have on the public, we urge EPA to provide the public at least 30 days to provide comments based on a full record. We likewise urge the agency to make public all information that is not expressly protected from disclosure by TSCA § 14 as expeditiously as possible, and not to commence the period provided for public comment until all that information has been disclosed and made electronically accessible in the docket. Allowing the public only 15 days to prepare and submit comments on a new proposal allowing the use of a chemical substance with known hazards is inherently arbitrary and capricious.

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EPA’s compressed timeframe, affording a mere 15 days from the publication in the Federal Register on February 8, 2018, to the close of comments on February 23, 2018, is manifestly unreasonable. The time constraints limit a commenter’s ability to develop more detailed assessments of the adequacy of the conditions specified in the amended SNUR. EPA’s incredibly compressed timeframe for input violates the APA because it limits the quality and depth of commenters’ participation in the rulemaking process in a manner that does not match the complex, technical, and consequential nature of the rule.

Ultimately, cutting off public comment in this manner is harmful to EPA’s own deliberation and the quality of any final action. Stakeholder engagement is vital to “test” a proposed policy, by identifying potential flaws in and improvements to a proposal. And the appearance that EPA is trying to “ram through” a new use for a hazardous chemical substance without adequate scrutiny undermines the credibility of the entire TSCA program.

We appreciate your consideration of our concerns, and we urge you to act quickly to ensure the public has a full and fair opportunity to comment on these important issues. Given the compressed time frame, we request a ruling on this extension request within three business days.

Respectfully submitted,

/s/ Robert P. Stockman

Robert P. Stockman

Senior Attorney

Environmental Defense Fund

1875 Connecticut Avenue, NW, Suite 600

Washington, DC 20009

(202) 572-3398

rstockman@edf.org

cc.

Maria Doa, Director, Chemical Control Division, Office of Pollution Prevention and Toxics
Greg Schweer, Chief, New Chemicals Management Branch, Chemical Control Division, Office of Pollution Prevention and Toxics

Kenneth Moss, Team Leader, New Chemicals Program, Chemical Control Division, Office of Pollution Prevention and Toxics

Brian Grant, Acting Associate General Counsel, Pesticides and Toxic Substances Law Office, Office of General Counsel