



Comments on
Certain Nonylphenols and Nonylphenol Ethoxylates; Significant New Use Rule
EPA-HQ-OPPT-2007-0490; FRL-9912-87
79 Federal Register 59186-59195 (Wednesday, October 1, 2014)
Submitted January 15, 2015

Summary

Environmental Defense Fund (EDF) supports EPA’s proposal to promulgate a significant new use rule (SNUR) addressing certain nonylphenols (NPs) and nonylphenol ethoxylates (NPEs). We respectfully submit these comments that urge EPA, in finalizing this SNUR, to:

1. explain the status and disposition of earlier EPA proposals for promulgation of test rule(s) for NPs and NPEs, and the rationale for any decisions made to pursue, delay or not pursue such testing;
2. include a full discussion of human health alongside aquatic toxicity concerns associated with NPs and NPEs in explaining EPA’s rationale for the SNUR;
3. clearly document the process EPA used to identify which NPs and NPEs are in and are not in commerce and how it selected the 15 NPs and NPEs that are the subject of the proposed SNUR;
4. describe what regulatory or other actions the Agency is taking, is considering taking, or intends to take, to identify and address potential risks associated with ongoing uses of NPs and NPEs that are not subject to the SNUR; and
5. correct the statement of the Agency’s rationale as to why Executive Order 13045 does not apply to the SNUR, which erroneously states that the SNUR “is not intended to address environmental health or safety risks affecting children.” The appropriate rationale should be “because it is not an economically significant rule as defined by Executive Order 12866.”

Introduction

Environmental Defense Fund (EDF) strongly supports EPA’s proposed SNUR, designating any use as a “significant new use” for 13 NPs and NPEs, and any use other than use

as an intermediate or epoxy cure catalyst as a “significant new use” for two additional NPs. Finalization of this rule would require those subject to the rule to notify EPA before manufacturing, importing, or processing these 15 NPs and NPEs in order to allow for EPA to evaluate associated potential risks.

NPs and NPEs are highly toxic to aquatic organisms and evidence indicates they are exhibit endocrine-disrupting (estrogenic) properties. Further, studies in rodents indicate the potential for reproductive and developmental toxicity. Promulgation of a SNUR is one of a number of steps needed to reduce or prevent human and environmental exposures to NPs and NPEs.

We have provided detailed comments below.

Response to Request for Public Comment

- I. In promulgating the final SNUR, EPA should explain the status and disposition of earlier EPA proposals for promulgation of test rule(s) for NPs and NPEs, and the rationale for any decisions made to pursue, delay or not pursue such testing.

The impetus for initiating regulatory action under TSCA for NPs and NPEs came in response to a petition filed under Section 21 of TSCA in 2007, titled *Citizen Petition to EPA Regarding Nonylphenol and Nonylphenol Ethoxylates*.¹ Among other requests, the petitioners asked EPA to exercise its authority under TSCA Section 4 to “[r]equire manufacturers and importers to conduct specific health and safety studies” for NPs and NPEs.

In response to the petition, in 2009 EPA published an advanced notice of proposed rulemaking (ANPRM) for aquatic and sediment toxicity testing for NPs and NPEs and requested comments on gathering data to evaluate industrial laundry workers exposure to NPEs.² In 2010, EPA issued its *Nonylphenol (NP) and Nonylphenol Ethoxylates (NPE) Action Plan* outlining

¹ *Re: Citizen Petition to EPA Regarding Nonylphenol and Nonylphenol Ethoxylates*. June 5, 2007. Petitioners: Sierra Club, Environmental Law & Policy Center, Washington Toxics Coalition, Pacific Coast Federation of Fisherman’s Associations, Physicians for Social Responsibility, and UNITE HERE.

² *Testing of Certain Nonylphenol and Nonylphenol Ethoxylates Substances*, 74 Fed. Reg. 28654.

EPA's plan to simultaneously propose a SNUR and a test rule for NPs and NPEs.^{3,4} According to information made publically available through OIRA, EPA planned to propose the combined SNUR and test rule by August 2012.⁵

EDF supported EPA's intent to initiate a test rule for NPs and NPEs in addition to a SNUR. As outlined in the citizens' petition, there are a number of important data gaps with regards to these chemicals. The hazard data that would be provided for NPs and NPEs subject to a test rule would prove valuable for informing future regulatory decisions, including making regulatory determinations in response to receipt of Significant New Use Notifications (SNUNs).

However, the SNUR recently proposed by EPA does not even mention the earlier intent and steps taken toward promulgating a test rule. In finalizing this SNUR, EDF requests that EPA clearly articulate the status of any test rule development. EPA should clarify what information it has and does not have on NPs and NPEs, and whether it considers information it does have to be adequate to characterize potential human health and environmental risks and to inform and support further actions on these chemicals by the Agency. EPA should also clarify the timeline for proposal of any test rule(s) it anticipates promulgating.

II. EPA should include a full discussion of human health alongside aquatic toxicity concerns associated with NPs and NPEs in explaining EPA's rationale for promulgating the SNUR.

In finalizing this SNUR, EDF requests that EPA include a discussion of potential human health effects from exposure to NPs and NPEs. While the evidence is strong that NPs and NPEs have endocrine-disrupting (estrogenic) properties in aquatic species, there is also evidence to

³ EPA, *Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan*. [RIN 2070-ZA09]. August, 18, 2010. Available at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf.

⁴ Note that EDF has supported an approach that EPA has proposed in the past of developing a combined SNUR and test rule as an efficient approach to gaining needed information. See EDF's joint comments on the proposed test rule and SNUR for Certain High Production Volume Chemicals: <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0520-0055>.

⁵ See: <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=2070-AJ34>.

suggest that these effects may occur in mammalian species.^{6,7} Furthermore, studies in rodents indicate the potential for reproductive and developmental toxicity.⁸ However, the proposed SNUR does not even mention human health concerns and instead focuses exclusively on aquatic toxicity, which is inconsistent with both the original citizens' petition and EPA's own communications.

In addition to aquatic toxicity, the 2007 citizens' petition emphasizes potential human health effects from exposure to NPs and NPEs and requested that EPA promulgate test rules to fill data gaps relevant to human health. The authors state that "Fish may not be alone in responding in potentially dangerous ways to NP. Research published in the September 2006 edition of *Toxicological Sciences* shows that human placenta responds to NP in the first trimester. The results may be early termination of pregnancy and fetal growth defects." The petition requested three test rules specifically to fill data gaps on human health effects and exposure levels: testing for levels of NPs and NPEs in humans and estrogenic effects on the development of the human placenta, testing for health impacts in occupational workers in the industrial laundry industry through epidemiology studies, and testing to determine human exposure to NPEs in residential indoor air.

Although in its response⁹ to the citizens' petition EPA denied the petitioners' request for these three test rules related to human health effects and exposure, the Agency acknowledges there is evidence for potential human health effects and indicates EPA's intent to evaluate these effects. For example, in the explanation denying testing for estrogenic effects on the development of the human placenta, the response states:

Reproductive studies of NP in mammals have been conducted (Refs. 17 and 18), as well as other studies which have examined the estrogenic effects of NP in mammals (e.g., uterotrophic assay) (Refs. 19, 20, and 21), and, on the basis of these data, EPA believes it has sufficient information to evaluate NP's reproductive risks to human health without conducting a non-standard placental study of the type requested by petitioners.

⁶ Legler, J., Van Den Brink, C.E., Brouwer, A., et al. Development of a stably transfected estrogen receptor-mediated luciferase reporter gene assay in the human T47D breast cancer cell line. *Toxicological Sciences*, Volume 48, 1999, pp. 55-66.

⁷ Balaguer, P., Franois, F., Comunale, F., et al. Reporter cell lines to study the estrogenic effects of xenoestrogens. *Science Total Environment*, Volume 233, 1999, pp. 47-56.

⁸ See: <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/np-npe.html>

⁹ *TSCA Section 21 Petition on Nonylphenol and Nonylphenol Ethoxylates; Response to Citizens' Petition*, 72 Fed. Reg. 50954.

Furthermore, while EPA did not grant the petitioners' request for an epidemiological study of NPE exposure in industrial laundry workers due to its expectation that exposure potential from liquid detergents would be low, the Agency did acknowledge inhalation exposure concerns for the fraction of industrial and institutional laundry operations that use powdered detergents. Accordingly, in the ANPRM published in 2009, EPA solicited comments on the best methods to gather data on industrial laundry workers' exposure to NPs and NPEs in both types of detergents.¹⁰

There are additional indications of the Agency's concern and evidence for potential human health effects of NPs and NPEs. Following the Deep Water Horizon Spill in April 2010, EPA's National Center for Computational Toxicology and the National Institutes of Health's (NIH) Chemical Genomics Center jointly published a study assessing the estrogenic and androgenic potential of eight oil spill dispersants in three mammalian cells types. The study used a number of NPs and NPEs as reference chemicals, and, as expected, found estrogen receptor activity in the NP and NPE assays (branched NP was the most potent).¹¹ Further, the introduction of the study states that "NPEs can degrade to produce nonylphenol, which can strongly interact with the estrogen receptor,"¹² and cites a number of other studies finding similar results in a variety of species, including rats.¹³

The potential for human health effects and human exposure are both also explicitly highlighted in EPA's 2010 NPs and NPEs Action Plan¹⁴ as well as on the associated website.¹⁵ Both state that "NP has also been detected in human breast milk, blood, and urine and is

¹⁰ *Testing of Certain Nonylphenol and Nonylphenol Ethoxylates Substances*, 74 Fed. Reg. 28654.

¹¹ Judson, R. S., Martin, M. T., Reif, D., et al. Analysis of Eight Oil Spill Dispersants Using Rapid, In Vitro Tests for Endocrine and Other Biological Activity. *Environ. Sci. Technol.*, Volume 44, July 2010, pp. 5979-5985.

¹² *Id* Volume 44, July 2010, pp. 5979-5985.

¹³ Kanno J., Onyon, L., Peddada, S., et al. The OECD Program to Validate the Rat Uterotrophic Bioassay. Phase 2: Dose-Response Studies. *Environmental Health Perspectives*, Volume 111, September 2003, pp. 1530-1549.

¹⁴ EPA, *Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan*. [RIN 2070-ZA09]. August, 18, 2010. Available at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf.

¹⁵ EPA, *Nonylphenol and Nonylphenol Ethoxylates*. Available at <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/np-npe.html> (last visited November 25, 2014).

associated with reproductive and developmental effects in rodents.” The Action Plan cites a number of effects identified in rodents, including reduced sperm counts, increased estrous cycle length, and decreased ovarian weights. Additionally, the Action Plan indicates that EPA intends “to evaluate the potential for disproportionate impact of exposure to NP and NPEs on children and other sub-populations.” Since publication of the Action Plan, several studies on human exposure to NPs and NPEs have been published, including (but not limited to):

- 1) Gyllenhammer, I., Glynn, A., Darnerud, P. O. Lingell, S., van Delft, R., Aune, M. 4-Nonylphenol and bisphenol A in Swedish food and exposure in Swedish nursing women. *Environment International*, Volume 43, August 2012, pp. 21–28.¹⁶
- 2) Li, X., Ying, G., Zhao, J., Chen, Z., Lai, H., and Su, H. 4-Nonylphenol, bisphenol-A and triclosan levels in human urine of children and students in China, and the effects of drinking these bottled materials on the levels. *Environment International*, Volume 52, February 2013, pp. 81–86.¹⁷
- 3) Raecker, T., Thiele, B., Boehme, R. M., and Guenther, K. Endocrine disrupting nonyl- and octylphenol in infant food in Germany: Considerable daily intake of nonylphenol for babies. *Chemosphere*, Volume 82, Issue 11, March 2011, pp. 1533–1540.¹⁸

Despite growing evidence of human exposure and EPA’s acknowledgement that there is concern for human health effects, the rationale for the proposed SNUR does not even mention human health concerns. Even if there is sufficient information to justify promulgating a SNUR based solely on aquatic toxicity, EDF strongly urges EPA to include a full discussion of human health in the final SNUR, for the following reasons:

- There is clear evidence for potential human health effects from exposure to NPs and NPEs. In promulgating the final SNUR, EPA should acknowledge these potential health effects by including a discussion of mammalian toxicity studies and human exposure potential, along with aquatic toxicity and exposure concerns, as providing a basis for the SNUR.
- Reviews EPA conducts of SNUNs should not be limited to aquatic toxicity and exposure. EDF is concerned that limiting the scope of the SNUR to aquatic risks may limit EPA’s ability to review NPs and NPEs for potential human health effects and exposures. By including human health in the rationale for the rule, EPA will create a

¹⁶ Available at <http://www.ncbi.nlm.nih.gov/pubmed/22466019>.

¹⁷ Available at <http://www.ncbi.nlm.nih.gov/pubmed/21794921>.

¹⁸ Available at <http://www.ncbi.nlm.nih.gov/pubmed/21185059>.

broader and more defensible basis not only for issuing the SNUR, but also for evaluating SNUNs for human health concerns.

- The potential for endocrine disruption in humans from NP and NPE exposure is an important data gap that warrants discussion in the final SNUR. Given the well-established endocrine-disrupting properties of NPs and NPEs, and indications, as discussed above, that these effects may occur in humans, EPA should prioritize steps to fill this data gap, including through promulgation of a test rule. As noted previously with respect to aquatic toxicity, in finalizing the SNUR, it is essential that EPA is transparent about information it has and does not have regarding the potential for these chemicals to have endocrine-disrupting properties in humans, whether EPA considers the information it has to be adequate to characterize potential human health concerns, and actions the Agency intends to take in order to obtain needed data.

If EPA were to decide that a full discussion of human health concerns as a basis for the SNUR is not warranted, it should articulate its rationale for focusing exclusively on aquatic concerns. Even in such a case, however, EPA should make clear its authority and intent to consider human health concerns in reviewing any submitted SNUN. Currently the preamble to the proposed rule notes that its review of any SNUNs received could include human health concerns.¹⁹ However, inclusion of an explicit statement is necessary in finalizing the SNUR that EPA is aware of potential human health concerns and that future reviews of activities proposed under TSCA involving NPs and NPEs would not be limited *a priori* to aquatic concerns.

III. The final SNUR should clearly document the process EPA used to identify which NPs and NPEs are in and are not in commerce and how it selected the 15 NPs and NPEs that are the subject of the SNUR.

EDF requests that EPA include more information in the final rule describing the selection process for the 15 NPs and NPEs addressed through this rule. While the proposed rule partially explains the process for ascertaining whether the 15 selected NPs and NPEs are currently in

¹⁹ See Section VII. Test Data and Other Information: “SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on: 1. Human exposure and environmental releases that may result from the significant new uses of the chemical substance...” and Section X. Alternatives: “First, if EPA were to require reporting under TSCA section 8(a) reporting for new uses instead of TSCA section 5(a), then EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA sections 5(e) or 5(f) to prohibit or limit the activity before it begins.”

commerce, it is unclear how these 15 NPs and NPEs were originally identified and the extent to which other NPs and NPEs are in commerce and have ongoing uses that place them outside the reach of the SNUR.

Without doing so, readers cannot understand whether or not EPA conducted a comprehensive search for all NPs and NPEs potentially in production. Through discussion with EPA staff, it is EDF's understanding that EPA started with a search of the TSCA inventory for all NPs and NPEs, which identified 17 NPs and NPEs, and that two branched NPEs were excluded from the SNUR due to their current widespread use. EDF requests that EPA explain this selection process in the final rule so that it is clear that EPA considered all NPs and NPEs for inclusion in the present SNUR.

EPA should also more fully explain how it ascertained that 13 of the NPs/NPEs are not in U.S. commerce, in light of the incomplete nature of reporting under EPA's Chemical Data Reporting (CDR) rule (due to exemptions and a per-site volume threshold) and other information suggesting their commercial availability.²⁰

IV. EPA should describe what additional regulatory or other actions the Agency is taking, is considering taking, or intends to take, to identify and address potential risks associated with ongoing uses of NPs and NPEs that are not subject to the SNUR.

It is EDF's understanding that there are four NPs and NPEs on the TSCA Inventory that are not addressed, or are only partially addressed, through the SNUR: 4-nonylphenol (CASRN 84852-15-3); 2-nonylphenol (CASRN 91672-41-2); Poly(oxy-1,2-ethanediyl), a-(4-nonylphenyl)-w-hydroxy-, branched (CASRN 124087-87-0); and Poly(oxy-1,2-ethanediyl), a-(nonylphenyl)-w-hydroxy-, branched (CASRN 68412-54-4).

4-nonylphenol and 2-nonylphenol are branched NPs, which EPA indicates are currently used as intermediates and epoxy cure catalysts in the proposed SNUR. Poly(oxy-1,2-ethanediyl), a-(4-nonylphenyl)-w-hydroxy-, branched and Poly(oxy-1,2-ethanediyl), a-

²⁰ Bergeson & Campbell PC, *Regulatory Developments: EPA Proposes SNUR for Nonylphenols and Nonylphenol Ethoxylates*. October 2, 2014. Available at: <http://www.lawbc.com/regulatory-developments/entry/epa-proposes-snur-for-nonylphenols-and-nonylphenol-ethoxylates/>. (Last visited Nov 13, 2014).

(nonylphenyl)-w-hydroxy-, branched are branched NPEs that have widespread commercial use (although they are not identified or discussed in the proposed rule). The most recent information contained in the downloadable version of data EPA collected under its CDR rule²¹ indicates the following 2011 production and importation volumes for these branched NPs and NPEs:

Branched NPs in Commerce (in Proposed Rule)

CASRN	Company Name	Domestically Manufactured (lbs)	Imported (lbs)
84852-15-3	SOLVCHEM INC	46,915	0
84852-15-3	HUNTSMAN CORP	0	CBI
84852-15-3	SI GROUP INC	CBI	0
84852-15-3	CBI	CBI	0
84852-15-3	ICC INDUSTRIES	13,170,499	214,620
84852-15-3	SI GROUP INC	CBI	0
91672-41-2	ICC INDUSTRIES	1626894	0

Branched NPEs in Commerce (Not in Proposed Rule)

CASRN	Company Name	Domestically Manufactured (lbs)	Imported (lbs)
127087-87-0	SOLVCHEM INC	Withheld	Withheld
127087-87-0	NORMAN FOX & CO	Withheld	Withheld
127087-87-0	CHEMORSE LTD	Withheld	Withheld
127087-87-0	BARBE AMERICA INC	CBI	CBI
68412-54-4	CHEMORSE LTD	731,802	0

Although we fully recognize that ongoing uses of a chemical cannot be addressed through the SNUR, EDF urges EPA to include a full discussion of the status of production and use of these four NPs and NPEs and EPA’s data needs and anticipated actions to identify and address potential risks. The ongoing uses of branched NPs and NPEs warrant attention, given a) NPEs can break down into NPs, as mentioned above, and b) the Judson et al., 2010 study indicates that a branched NP (CASRN 84852-15-3) has the most potent estrogenic effects among studied NPEs and NPs. EPA should address the following questions:

- Does EPA have sufficient data on the potential health and environmental effects, environmental fate and potential for exposure to these chemicals?
- If not, what steps is EPA taking or planning to take to secure sufficient data? Are test rules contemplated?
- If so, is there evidence of significant risk to human health or the environment from ongoing uses of these chemicals?

²¹ Available at <http://www.epa.gov/cdr/>. EDF understands that EPA believes there may be some misreporting of NPs and NPEs on the CDR.

- If so, what next steps, including regulatory action, does EPA anticipate taking, and when?

Furthermore, it appears that the Agency has not taken any steps to address industrial laundry workers' potential exposure to NPs and NPEs in detergents beyond releasing the ANPRM in 2009 requesting information on methods for gathering exposure data. In response to this request, EPA received comments from Environmental Law and Policy Center, Workers United, and Sierra Club indicating the need for exposure monitoring data in industrial laundry workers and implementation of use restrictions to protect this population.²² EPA should make available what it has learned about potential exposure to NPs and NPEs in industrial laundry workers through the ANPRM as well as any additional steps it has taken, or plans to take, to address these concerns.

EDF understands that EPA is encouraging the voluntary phase out of NPEs in industrial laundry detergents through its Safer Detergents Stewardship Initiative (SDSI) under the Design for the Environment (DfE) Program.^{23,24} According to EPA's Nonylphenol and Nonylphenol Ethoxylates website, EPA has expectations that the phase-out will end the use, at least among signatories to the agreement, of NPEs in industrial laundry powder detergents by 2014.²⁵ Has the phase out in fact been successful in eliminating these uses? Has EPA decided not to pursue testing of exposure in industrial laundry workers because it is no longer expected to be a concern due to SDSI? These questions warrant discussion in the context of EPA's finalization of this proposed SNUR.

V. EPA should correct the statement of the Agency's rationale as to why Executive Order 13045 does not apply to the SNUR, which erroneously states that the SNUR "is not

²² *Re: EPA-HQ-OPPT-2007-0490, Federal Register/Vol. 74, No. 115/ Wed. June 17 2009.* September 2009. Commenters: Environmental Law and Policy Center, Workers United – An SEIU Affiliate, and Sierra Club.

²³ EPA, *Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan*. [RIN 2070-ZA09]. August, 18, 2010. Available at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf.

²⁴ See <http://www.epa.gov/dfe/pubs/projects/formulat/dfeFactSheet.pdf>.

²⁵ EPA, *Nonylphenol and Nonylphenol Ethoxylates*. Available at <http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/np-npe.html> (last visited November 25, 2014).

intended to address environmental health or safety risks affecting children.” The appropriate rationale should be “because it is not an economically significant rule as defined by Executive Order 12866.

Executive Order (EO) 13045 only applies to rules that are determined to be economically significant under EO 12866.²⁶ According to Section XIII.A of the proposed SNUR, EPA notes that the proposed NPs and NPEs SNUR is not considered a significant regulatory action under EO 12866.

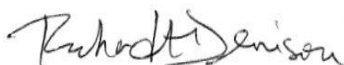
However, Section XIII.G. of the proposed SNUR reads, “This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks affecting children.”

The statement that the SNUR is “not intended to address environmental or safety risks affecting children” could be read as implying that EO 13045 is not applicable because children are not at risk from NPs and NPEs – contradictory to the statement in the 2010 NPs and NPEs Action Plan that EPA intends “to evaluate the potential for disproportionate impact of exposure to NP and NPEs on children and other sub-populations.”

Given that the SNUR is not subject to EO 13045 because it is not a significant regulatory action under EO 12866, Section G should accordingly be revised to read: “This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it is not an economically significant rule as defined by Executive Order 12866.”

EDF appreciates the opportunity to provide these comments to the Agency on this important proposed rule.

Sincerely,



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²⁶ Exec. Order No. 13045, 3 C.F.R. 19885 (1997). Print.