May 4, 2017

The Hon. Scott Pruitt
Administrator, U.S. Environmental Protection Agency
EPA Docket Center
Mail Code 28221T
1200 Pennsylvania Ave., NW
Washington, DC 20460

**Attn: Docket ID No. EPA-HQ-OA-2017-0190**

**Re: Comments regarding EPA's implementation of Executive Order 13777, "Enforcing the Regulatory Reform Agenda," as it relates to Title I of the Toxic Substances Control Act.**

The direction charted by EPA Administrator Scott Pruitt is devastating for human health and represents an unprecedented assault on our critical health and environmental protections. Environmental Defense Fund (EDF) vigorously opposes any weakening of health and environmental safeguards. Americans strongly support health and environmental protection and stand united in opposition to rollbacks of these protections for families and communities.

In these comments, EDF addresses the importance of the agency's recent actions taken under, and steps taken to implement, Title I of the Toxic Substances Control Act (TSCA), as recently updated by the Frank R. Lautenberg Act for Chemical Safety for the 21st Century Act ("Lautenberg Act").

EDF has separately submitted to this docket additional comments addressing the importance of EPA Clean Air Act regulations to protect public health[1] as well as specific comments on EPA regulations to reduce children's exposure to lead-based paint pursuant Title IV of TSCA.[2]

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1 EDF comments: "Comments of Environmental Defense Fund on EPA's request for public input(82 Fed. Reg. 17,793) related to the agency's implementation of Executive Order 13,777, issued 2/24/17 (82Fed. Reg. 12,285), directing agencies to establish a Regulatory Reform Task Force to oversee the evaluation of existing regulations to make recommendations about potential repeal, replacement, or modification."

2 EDF comments: "Re: Comments regarding EPA's implementation of Executive Order 13777, "Enforcing the Regulatory Reform Agenda," as it relates to Title VI of the Toxic Substances Control Act, Docket No. EPA-HQ-OA-2017-0190-0042."

## Introduction

EDF is deeply concerned about the "regulatory reform" process called for by the February 24 Executive Order 13777 (EO process). EPA needs to continue to focus on taking early health-protective actions and implementing the Lautenberg Act as Congress directed last year. If the Administration uses the EO process to skew or take apart the delicately balanced approach to chemical safety set in motion by the Lautenberg Act, it will further exacerbate the public's concerns about the safety of chemicals and do nothing to provide the stability that the business community sought through TSCA reform.

Last year, Congress enacted the Lautenberg Act with strong bipartisan support, which amended the core provisions of the 1976 Toxic Substances Control Act (TSCA) for the first time ever. It was passed based on a broad acknowledgment that our federal chemicals management system was fundamentally not working, and that both the public and the business community needed more rigorous and effective oversight and regulation of chemicals, not less. The agency is just starting to implement the new system mandated by Congress not even a year ago to better protect the public's health from toxic chemical exposure and to restore lost confidence.

Confidence in the safety of chemicals among the public and in the marketplace is at an all-time low. The public is concerned about the chemicals they encounter every day, and is demanding more scrutiny and assurance of safety of chemicals used to make the products brought into their homes, schools, and places of work. Product manufacturers are applying restrictions on the use of certain chemicals in their own products. Major retailers, including Walmart, Target, and CVS, are stepping up with strong corporate policies on toxic chemicals. Much of this effort emerged in compensation for a void at the national level, the result of ineffective federal chemicals laws that hadn't been updated for decades. Scientific advances increasingly allow us to better understand how we are exposed to chemicals every day and how they impact our health, particularly when exposures happen early in life. Yet TSCA prior to its reform failed both to generate and provide access to the information needed to identify safe and unsafe chemicals, and to provide EPA with the authority it needed to mitigate harm from chemicals determined to be dangerous. Tens of thousands of chemicals were allowed to remain on the market without any review of their safety, and hundreds of new chemicals came on the market every year without any demonstration that they were safe.

The need for a credible regulatory agency—one able to make timely, independent, science-based decisions about chemical safety—was recognized as the shared goal of reforming TSCA. Under-regulation, not over-regulation, has been the clear problem in this arena. Taking anti-regulatory aim at TSCA's vital new protections, or tying the agency's hands in obtaining and using the best available science and scientific advice, will only further undermine public and market confidence in EPA and further erode trust in the industry and the safety of its products.

Under the guise of reforming regulation to improve government efficiency, this anti-regulatory process is opening the door for the agency to turn its back on strong science and public health protection. We already see a common theme emerging: Anytime the science points to a problem with a specific

chemical, claims are asserted that the science is "flawed." But polluters, who have a vested interest in avoiding regulation of its chemicals, should not get to determine what constitutes good science. EPA's role is to independently make science-based decisions on behalf of the public – not the polluters.

We offer the following comments on some of the specific actions EPA has initiated or recently taken that are now under attack.

**Chemical-specific actions**

Prior to the passage of the Lautenberg Act, TSCA was so ineffective that EPA couldn't even ban asbestos – a known carcinogen. Now, under the new law, Congress has given EPA new tools it needs to review and manage the risk of chemicals and expressly authorized EPA to take early actions, based on broad agreement that such actions are necessary to demonstrate the new law was working and to begin to restore confidence in our federal chemical safety system.

The agency has proposed to restrict high-risk uses of three toxic chemicals, specifically: trichloroethylene (TCE) used as a spot cleaning agent in dry cleaning, as an aerosol spray degreaser in commercial and consumer settings,[3] and as a vapor degreaser in commercial settings;[4] and methylene chloride (DCM) and N-methylpyrrolidone (NMP) used in commercial and consumer paint and coating removal products.[5] These chemicals present real everyday health risks to American consumers and workers.

- Numerous authoritative bodies have classified TCE as a known human carcinogen, including the National Toxicology Program (NTP)[6], the Agency for Toxic Substances and Disease Registry (ATSDR),[7] EPA's Integrated Risk Information System (IRIS),[8] and the International Agency for Research on Cancer (IARC).[9] A 2013 review of thousands of scientific studies concluded that TCE is carcinogenic to humans by all routes of exposure, and poses a range of non-cancer health effects including immunotoxicity, neurotoxicity, and developmental toxicity including fetal cardiac defects.[10]

[3] 81 Federal Register 91592-91624. Proposed rule, "Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a)." See: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0001
[4] 82 Federal Register 7432-7461. Proposed rule, "Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a)." See: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0001
[5] 82 Federal Register 7464-7533. Proposed rule, "Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)." See: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0001
[6] See here: https://www.niehs.nih.gov/health/materials/tce_508.pdf
[7] See here: https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[8] See here: https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=199
[9] See here: http://monographs.iarc.fr/ENG/Monographs/vol106/mono106-001.pdf
[10] See here: https://ehp.niehs.nih.gov/1205879/



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- DCM is an acutely lethal substance. Use of DCM-based paint stripping products has led to documented deaths of *dozens* of workers over the past few decades.[11] DCM is likely carcinogenic in humans by a mutagenic mode of action, and is strongly linked to liver and lung cancers.

- NMP is often used as a substitute for DCM in paint and coating removal products, yet it also presents major health risks of its own – ranging from developmental and reproductive toxicity to neurotoxicity to liver and kidney damage. Studies demonstrate that prenatal exposure is linked to fetal death.

EPA clearly demonstrated the excessive risks posed by these uses of these chemicals in its 2014 peer-reviewed risk assessments[12] and has appropriately proposed to mitigate these risks through TSCA section 6 risk management rules, as required by law under the amended TSCA.

Congress expected EPA to act promptly to mitigate these risks by specifically authorizing it to issue rules pursuant to section 6(a) of TSCA. But now we're seeing some in industry take aim at these needed health protections.

For years, the Halogenated Solvents industry has attacked the underlying science on TCE's fetal cardiac effects. For example, the Halogenated Solvents Industry Alliance (HSIA) continues to raise the same scientific issues that have been repeatedly addressed by EPA and through peer review. Most recently, HSIA has sought a further delay, by requesting an inordinately long further extension in the comment period for EPA's proposed rule to restrict TCE's use as a vapor degreaser; the delay was requested in order to accommodate a new study it is sponsoring in an attempt to rebut a 14-year-old study EPA cited, even though this new study will not change EPA's unreasonable risk finding that is based on excessive risks for cancer and many other non-cancer endpoints beyond fetal cardiac malformations.[13] EPA decided to grant a shorter-than-requested extension.

HSIA's actions and those like it contribute directly to regulatory inefficiency. They also delay attainment of the substantial benefits this rule will provide: In EPA's proposed rule, it estimates that the ban of TCE's use as a vapor degreaser would result in monetized benefits ranging from $65 to $443 million (at a 3% discount rate on an annualized basis) over 20 years, a conservative estimate because it is based on reductions in ***cancer risks alone***.

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[11] See here: https://www.publicintegrity.org/2015/09/21/17991/common-solvent-keeps-killing-workers-consumers

[12] See Final EPA Work Plan Risk Assessments: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment (TCE), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-methylene (DCM), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment-n-0 (NMP).

[13] See EDF's letter opposing HSIA's request for an extension: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0387-0164

Some are also suggesting that these chemical risks can and should be managed through concentration limits, labeling, and reliance on personal protective equipment (PPE). But EPA has amply demonstrated that the real-world efficacy of such measures is highly variable and uncertain, and would be insufficient to mitigate the risk posed by these chemicals. Not to mention, these measures would be significantly more costly for industry to implement. For example, EPA's economic analysis[14] demonstrates that it would cost far *more* – on the order of $100 million more over 20 years – to implement such requirements for NMP than to comply with a simple ban.

Leadership at the agency needs to follow and act on the science – which clearly points to the unreasonable risks of these chemicals – and not allow companies with a vested interest in these toxic chemicals to derail these critical health protections. Initiating rollbacks of, or installing roadblocks to, these early actions – as some are now demanding – would fly in the face of this Congressional intent, and would set us all back to the very conditions of instability and unpredictability in the chemical regulatory landscape that led industry to seek reform of TSCA in the first place. That wouldn't be good for business or for the public's health. We strongly urge the agency to finalize its proposed bans on high-risk uses of TCE and DCM and also select the proposed ban option for NMP.

We also urge that EPA not interfere with the Formaldehyde Emissions Standards for Composite Wood Products final rule, which was mandated by Congress seven years ago.

**New chemical reviews**

With respect to EPA's implementation of the reformed TSCA's requirements for reviewing new chemicals,[15] while both EPA and the regulated community have suffered from growing pains, the picture is far less bleak than industry representatives claim, and many of their assertions are not accurate or are not consistent with or allowed by the new law.

- While there is a temporary backlog in EPA reviews of new chemicals, the backlog is shrinking, not growing. The backlog was the result of Congress making the law's new requirements immediately applicable. It is shrinking now that EPA has refined existing and developed new procedures to implement the new requirements, and has gained more staff resources to devote to the reviews.
- The new law expressly requires EPA to consider reasonably foreseen as well as intended uses of a new chemical in making its requisite risk finding. This is not optional as some in industry have suggested.
- Industry's call for EPA to revert back to prior practice of using significant new use rules instead of orders when it finds that reasonably foreseen uses of a new chemical may present unreasonable risk is simply not allowed under the new law.

[14] See EPA's economic analysis here: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0060
[15] See: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca



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- Congress intended that the rigor of new chemical reviews be significantly strengthened, and hence imposed a new requirement that EPA make an affirmative risk finding for each new chemical. So it is not surprising that more new chemicals are being subject to orders than was the case under the old law.
- The new law expressly requires EPA to impose conditions through an order on a new chemical for which it lacks adequate information to make its requisite risk finding. Hence, it is not surprising that more new chemicals are being subject to testing than was the case under the old law.

Restoring confidence in our nation's chemical safety system requires that EPA provide greater assurance that new chemicals will be safe once they enter products and materials we use in our homes, schools and workplaces. The need to restore public and market confidence was the common ground that engendered the strong bipartisan and stakeholder support for the new TSCA, including its provisions governing new chemical reviews. EPA needs to be given a chance to do its job.

**TSCA Framework Rules**

The Lautenberg Act mandates that EPA develop three "framework" procedural rules to establish a robust system to identify, review, and manage chemicals in commerce within one year of the law's enactment: 1) procedures for prioritization of chemicals for risk evaluation, 2) procedures for chemical risk evaluation, and 3) TSCA inventory notification. EPA proposed all three of these rules in January of this year.[16,17,18]

It is vital for EPA to meet its June 22, 2017, statutory deadline to finalize these rules, as they establish processes that will require several years to begin to yield decisions on specific chemicals. Delaying final promulgation of these rules, and thus preventing the process from commencing in the timeframe Congress intended, will only serve to undermine public confidence in the new law, frustrate business interests in restoring confidence in the chemicals marketplace, and hamper EPA's ability to carry out its new mandates.

Therefore, EDF strongly believes that these rules should not be considered under the regulatory reform process called for by EO 13777. Not only are these rules mandated by law and not yet finalized, but stakeholders have had ample opportunity to comment on the rules, including on opportunities to create efficiencies. EPA held several stakeholder meetings[19] last summer, took public input on the development of the rules prior to their proposal, and provided at least 60 days for public comment on each of the proposed rules. EPA should proceed without delay in finalizing the framework rules mandated by the Lautenberg Act.

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[16] Proposed prioritization rule: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0001
[17] Proposed risk evaluation rule: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0001
[18] Proposed inventory rule: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0001
[19] See here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/meetings-and-webinars-amended-toxic-substances-control



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**Nanoscale material reporting rule**

In January of this year, after more than a decade of delay, EPA finalized a TSCA section 8 reporting rule that will finally allow EPA to obtain basic data on production, use, exposure, and hazards from those that manufacture or process nanoscale materials.[20]

Nanomaterials are a diverse category of materials defined mainly by their small size. They often exhibit unique properties that can allow for novel applications, but those same properties also present the potential for novel or enhanced negative impacts on health or the environment. For example, some nanomaterials can more easily penetrate biological barriers such as the cell wall than their bulk counterparts. Increasingly, research is demonstrating that these materials can penetrate the lung and lead to adverse pulmonary and respiratory effects due to their small size.[21]

This rule was long overdue. A panel of experts recommended that EPA pursue such a rule to gather basic data on nanomaterials in 2005 – over 11 years before the rule was finalized. Over the years, numerous expert bodies, including the National Academy of Sciences,[22] the National Nanotechnology Initiative,[23] and EPA's Office of Research and Development,[24] identified the need for these kinds of basic information on nanomaterials to understand and manage their potential risk.

The rule followed a voluntary reporting program on nanomaterials that proved unsuccessful. After one year, EPA had received submissions from a mere 29 companies and on only 123 nanomaterials – fewer than 10% of the nanomaterials on the market at the time.[25] Few additional data were received in the second and final year of the program. The paltry participation by the industry demonstrated that a regulation was necessary to acquire the needed data.

The reporting rule went through extensive review and public notice and comment over many years, and its scope and requirements were repeatedly reduced in order to lessen burdens on the private sector. (See the Appendix for more detail on the lengthy process leading to the finalized reporting rule.)

If anything, this rule could have been strengthened in several ways noted in our August 2015 comments on the proposed rule.[26] These recommendations were not adopted by EPA, likely to reduce burdens on companies subject to reporting requirements:

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[20] 40 CFR Part 704. See: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0137
[21] See here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3266021/
[22] NAS, 2012. A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials. Available here: https://www.nap.edu/catalog/13347/a-research-strategy-for-environmental-health-and-safety-aspects-of-engineered-nanomaterials
[23] See EDF blog: http://blogs.edf.org/health/2011/01/28/regulating-nanomaterials-to-life-not-death/
[24] See here: https://www.epa.gov/chemical-research/research-nanomaterials
[25] See here: https://www.oecd.org/unitedstates/42061387.pdf
[26] See here: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0122



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1. The final rule indicates that aggregates of nanoscale particles must fall within the 1-100 nanometer (nm) range to be reportable. We had urged that aggregates comprised of nanoparticles between 1-100 nm should be reported even if the aggregate itself is larger, given that such aggregates can often disaggregate in the environment or during use.

2. The final rule indicates that companies that submitted a pre-manufacture notice (PMN) for a nanoscale material at any time since 2005 do not have to report for that material. We had argued that EPA should have required submission of any new information on a nanomaterial developed since the PMN was reviewed even if after 2005.

3. The final rule exempts from reporting chemical substances that are "formed at the nanoscale as part of a film on a surface." EDF did not support this exemption, arguing that such films can break down or erode over time especially if exposed to the elements, potentially releasing the nanoscale materials.

The nanoscale material section 8 reporting rule was long overdue, and is critical to allow the agency to obtain basic risk-relevant information that the scientific community has long identified as needed to make sound, science-based decisions about which materials and uses present concerns and which do not.

In its reforms to TSCA, Congress recognized the need to expand, not contract, the information-gathering authorities granted to EPA. It would be simply unacceptable for EPA leadership to seek to preclude EPA from simply collecting the data they need to do their jobs and make decisions informed by the best science.

Sincerely,

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Lead Senior Scientist

Lindsay A. McCormick, MPH
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Jennifer McPartland, Ph.D
Senior Scientist



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**Appendix:**

Below find links to EDF materials and submitted comments on the specific topics discussed above.

1. Chemical specific actions
   - EDF comments on TSCA section 6 rule on TCE in spot cleaners and aerosol degreasers submitted to EPA: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0163-0172
   - EDF blog: http://blogs.edf.org/health/2017/03/31/epas-ban-on-high-risk-uses-of-trichloroethylene-needs-to-get-over-the-finish-line/
   - EDF blog: http://blogs.edf.org/health/2017/01/13/on-a-roll-epa-proposes-to-ban-or-restrict-two-highly-toxic-paint-stripping-chemicals/

2. New chemical reviews
   - EDF comments submitted to EPA: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0658-0028
   - EDF blog: http://blogs.edf.org/health/2016/12/02/new-chemicals-under-the-new-tsca-growing-pains-now-but-a-stronger-system-going-forward/

3. TSCA framework rules
   - EDF comments on prioritization procedural rule submitted to EPA: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0001
   - EDF comments on risk evaluation procedural rule submitted to EPA: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0001
   - EDF comments on inventory notification rule submitted to EPA: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0001
   - EDF blog: http://blogs.edf.org/health/2017/03/21/getting-the-framework-right-for-the-new-tsca-edf-comments-filed-on-key-epa-proposed-rules/
   - EDF blog: http://blogs.edf.org/health/2017/03/29/known-knowns-and-known-unknowns-getting-an-accurate-transparent-and-up-to-date-tsca-chemical-inventory/

4. Nanoscale material reporting rule
   - EDF blog: http://blogs.edf.org/health/2017/01/11/at-last-epa-promulgates-nanomaterial-reporting-rule/
   - EPA comments on proposed nanoscale reporting rule submitted to EPA: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0122
   - Infographic on nanoscale reporting rule history (see below)



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# The long and winding road toward nanomaterial reporting

The timeline below illustrates the more-than-decade-long history of EPA's attempts to collect basic information on production and use of nanomaterials in the U.S.

**2005**

### EPA announces intent to pursue voluntary reporting program

June: EPA holds first public meeting on nanomaterials to discuss voluntary reporting program.

### NPPTAC advises simultaneous mandatory reporting

November: Federal National Pollution Prevention and Toxics Advisory Committee (NPPTAC) calls on EPA to develop mandatory reporting rules alongside voluntary program. EPA ignored the advice.

**2007**

### EPA proposes policy and draft concept paper for voluntary program

July: EPA proposes not to consider new nanoscale forms of chemicals with bulk forms already in commerce as "new chemicals" under TSCA; and issues a draft concept paper for Nanoscale Materials Stewardship Program (NMSP).

**2008**

### EPA launches voluntary reporting program

January: EPA launches NMSP, seeking voluntary reporting on nanomaterials.

### EPA finalizes policy restricting its own authority

January: EPA finalizes policy on new nanoscale forms of chemicals already in commerce, precluding review as new chemicals.

**2009**

### EPA starts proposing SNURs on specific nanomaterials

June: EPA proposes first significant new use rules ("SNURs") to require companies who intend to manufacture, import, or process a few specific nanomaterials to notify EPA beforehand.

### EPA announces intention to develop a test rule

Spring: Regulatory agenda lists carbon nanotubes TSCA test rule as "long term action." The test rule later moves to the proposed rule stage, where it stays until 2012.

### NMSP gets a poor grade

January: EPA NMSP Interim Report notes EPA received submissions from only 29 companies on only 123 (fewer than 10%) of nanomaterials on the market. The NMSP formally ends at the end of 2009, with little more to show.

**2010**

### EPA finalizes first carbon nanotubes SNUR

September: EPA finalizes the first specific nanomaterials SNUR, covering multi-walled and single-walled carbon nanotubes.

(Continued below)



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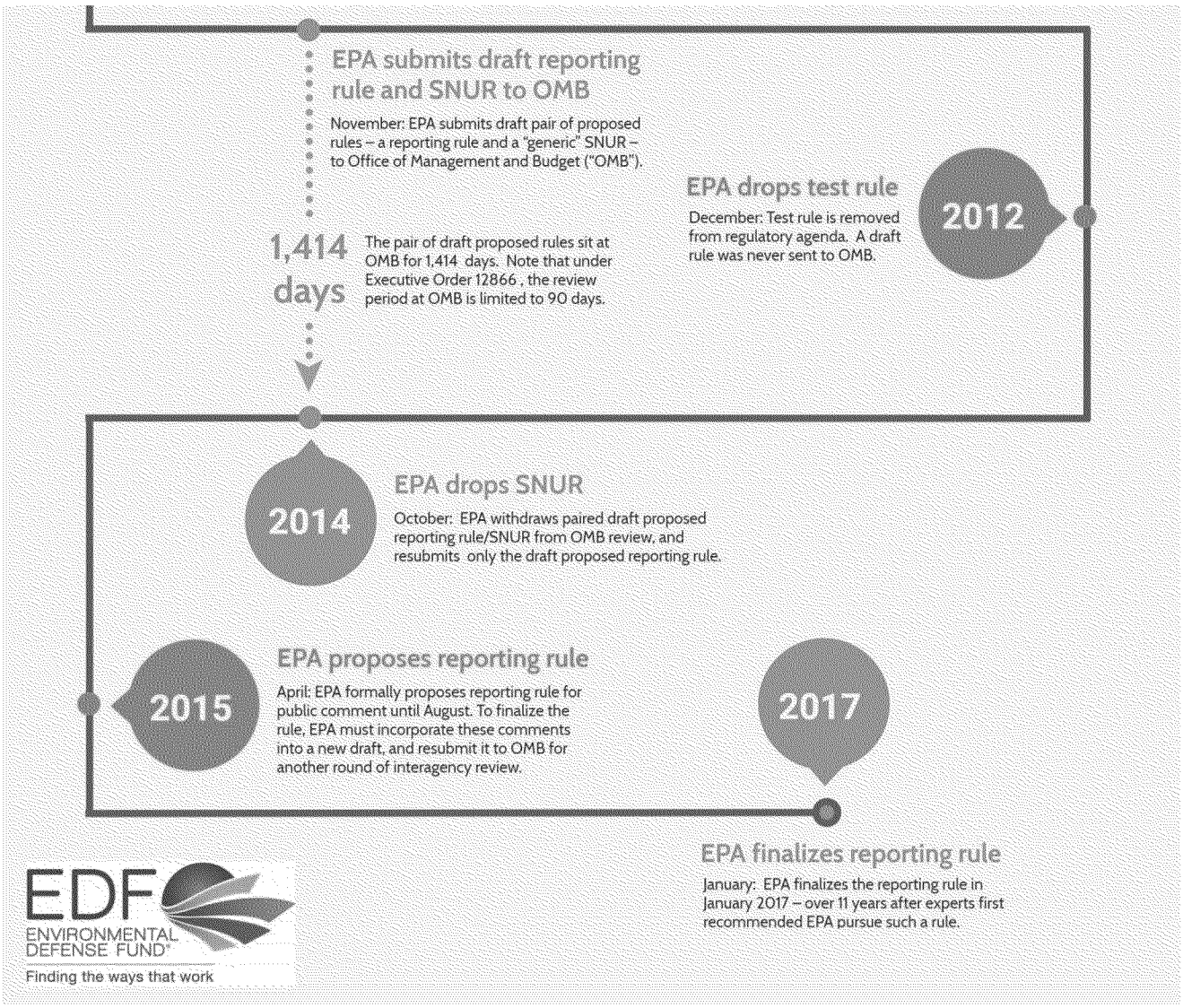
EPA submits draft reporting rule and SNUR to OMB
November: EPA submits draft pair of proposed rules – a reporting rule and a "generic" SNUR – to Office of Management and Budget ("OMB").
1,414 days
The pair of draft proposed rules sit at OMB for 1,414 days. Note that under Executive Order 12866 , the review period at OMB is limited to 90 days.
EPA drops test rule
December: Test rule is removed from regulatory agenda. A draft rule was never sent to OMB.
2012
2014
EPA drops SNUR
October: EPA withdraws paired draft proposed reporting rule/SNUR from OMB review, and resubmits only the draft proposed reporting rule.
2015
EPA proposes reporting rule
April: EPA formally proposes reporting rule for public comment until August. To finalize the rule, EPA must incorporate these comments into a new draft, and resubmit it to OMB for another round of interagency review.
2017
EPA finalizes reporting rule
January: EPA finalizes the reporting rule in January 2017 – over 11 years after experts first recommended EPA pursue such a rule.
EDF
ENVIRONMENTAL DEFENSE FUND
Finding the ways that work