reduced birth weight, reproductive toxicity, and cancer.[6] Like many PFASs, PCBs are known to be persistent, bioaccumulative, and toxic.

Finally, the attorneys general recommend a chemical family-based approach for listing PFASs on the TRI as it will provide critical information to enable the states, other regulators, and facility operators to better understand the use and potential for release of PFASs from regulated facilities. As a result, existing and future waste streams containing PFASs can be appropriately managed, remediated, and regulated, and uncontrolled releases can better be prevented to avoid adverse impacts to public health and the environment. Moreover, the cost of expanding reporting requirements for PFASs can be offset by the benefits of reducing environmental releases of these chemicals. For example, fugitive emission abatement tends to pay for itself in recovered materials.

Recommendation 2:

Add all PFASs to the TRI Program as individual listings to the extent that: (1) for each PFAS listed, a method to measure its level in drinking water has been validated by the Administrator; and (2) the chemical is not already listed pursuant to the NDAA.

EPA also should simultaneously list a number of individual PFAS chemicals to the TRI Program. The toxicity of PFOA and PFOS, the most studied PFASs to date, to humans and the environment is well known.[7] The recently enacted NDAA added several of the commonly recognized PFAS chemicals to the TRI Program, including PFOA and PFOS, along with GenX, PFNA, and PFHxS, together with certain salts and other compounds associated with each of these, and other PFASs identified under other statutes and regulations. NDAA, section 7321(b)(1). The state attorneys general commend Congress on this important first step.

For purposes of listing in the TRI, a number of additional PFASs may be reasonably anticipated to share the same hallmarks of persistence, bioaccumulation, and/or toxicity to humans as those already added to the TRI Program through the NDAA, with similar health-based effects at comparable exposure endpoints.[8] Compared to PFASs with well-known human health and environmental impacts, these additional PFASs may also be anticipated to accumulate in the environment with wide-ranging contamination in air, water, solids and multiple biological tissues, and/or break down to other PFASs whose impacts are known.[9] Many of these chemicals are readily measurable in drinking water using validated methods.

These individual PFASs easily meet EPCRA's criteria for listing to the TRI Program. The attorneys general urge EPA to exercise its authority to close the remaining regulatory gap for these PFASs. Consistent with the approach

implemented by Congress under the NDAA, these individual PFASs should be listed, along with their salt forms and closely-related chemicals (*e.g.*, linear and branched isomers).[10]

Recommendation 3:

The TRI Threshold Reporting Limit should be one pound for both individual PFAS chemicals and for the PFAS chemical compound category.

EPCRA establishes reporting thresholds of 25,000 pounds for facilities involved in manufacturing or processing listed chemicals, and 10,000 pounds for facilities that otherwise use listed chemicals. As the ANPRM recognizes, however, in the past EPA has established lower reporting thresholds for listed chemicals of special concern. EPA has also lowered reporting thresholds for persistent, bioaccumulative, and toxic (PBT) chemicals and chemical compound categories, and in particular, for PBTs with very high persistence and bioaccumulation values. 84 Fed. Reg. at 66371.

As discussed above, PFASs are well-understood to be highly persistent and bioaccumulative chemicals. Consequently, EPA should add individually-listed PFASs and the compound category of PFASs to the list of chemicals of special concern, ECPRA, section 372.28, and, at minimum, set a reporting threshold of 10 pounds (*i.e.*, for highly PBT chemicals). However, given their high potential for causing acute and chronic harm to humans and biota, in addition to their high persistence and bioaccumulative tendencies, the state attorneys general recommend that EPA set a threshold reporting requirement of one pound for PFASs.

A lower reporting threshold for PFASs is not without precedent. EPA has lowered the threshold reporting requirements for 16 PBT chemicals and five PBT categories due to the insidious threats PBTs pose compared to other chemicals in the TRI Program.[11] Of these, EPA has set reporting thresholds of 10 pounds for 10 PBT chemicals and one PBT category. Going further, EPA lowered the reporting threshold for the PBT chemical compound category of Dioxin and Dioxin-Like Compounds, to one tenth of a gram (0.0002205 pounds).[12]

A reporting threshold of one pound for both individual PFAS chemicals and the chemical compound category of PFASs is appropriate and warranted. For PCBs, a category of 209 individual PBT chemical compounds, EPA established an updated TRI reporting threshold of 10 pounds in 1999. Federal drinking water limits established by EPA are an order of magnitude lower for PFASs than for PCBs. Applying the same ratio, the TRI reporting threshold for PFASs should be an order of magnitude lower than for PCBs, *i.e.* one pound.[13]

Work by the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR) also supports a one-pound reporting threshold for PFASs. ATSDR derived a health-based screening level for total PCBs and has proposed draft health-based screening levels for four individual PFASs which are at or an order of magnitude lower than the health-based screening levels previously established for PCBs.[14] This justifies setting a reporting threshold for PFASs at one pound, roughly an order of magnitude lower than the ten-pound reporting threshold for PCBs.

Conclusion

The attorneys general appreciate this opportunity to comment on this ANPRM, and look forward to a future rulemaking that incorporates the recommendations set forth herein.

Sincerely,

[INSERT SIGNATURE BLOCKS]

End Notes

[1] July 30, 2019 Letter of State Attorneys General, *available at*: [https://ag.ny.gov/sites/default/files/multistate_pfas_legislative_letter_7.30.19_final.pdf].

[2] Comparison of toxicity for perfluoroalkyl substances is complicated due to limited studies, differences between genders, across species, and in mechanism of endpoint for specific chemicals, however, similarities exist in terms of association of specific health risks to multiple chemicals within the PFASs family. Suggested associations in humans include pregnancy-induced hypertension (PFOA and PFOS), hepatic effects (PFOA, PFOS and PFHxS), cholesterol effects (PFOA, PFOS, PNFA and PFDA), thyroid disease (PFOA and PFOS), antibody response (PFOA, PFOS, PFHxS and PFDA), asthma (PFOA), developmental effects (PFOA and PFOS) and death (PFOA and PFOS) (ATSDR 2018). Multiple replacement PFASs (6:2 chlorinated polyfluorinated ether sulfonate (6:2 Cl-PFESA), HFPO trimer acid (HFPO-TA), HFPO tetramer acid (HFPO-TeA), and 6:2 fluorotelomer sulfonic acid (6:2 FTS)) have been shown to have greater toxic effects on the human liver HL-7702 cell line, as compared to PFOA and PFOS (Sheng et al. 2018a).

ATSDR reviewed 187 animal studies and found that primary effects from exposure to perfluoroalkyl substances included hepatic (PFOA, PFOS, PFBA, PFHxA, PFHpA, PFNA, PFDA, PFUnA, PFDoA, PFBS and PFHxS), developmental (PFOA, PFOS, PFBA, PFHxA, PFNA, PFDA, PFUnA, PFDoA and PFHxS), and immune toxicity (PFOA, PFOS), though not all effects were observed or examined for the fourteen PFASs ATSDR evaluated. Additional effects were also found in laboratory animals relating to the kidney (PFHxA, PFUnA, PFBS and PFHxS), thyroid functioning (PFBA and PFHxS), and death (PFHxA, PFNA and PFDA) (ATSDR 2018). Compared to PFOA, HFPO-TA showed greater liver toxicity and bioaccumulation potential in mice (Sheng et al. 2018b).

Human biomonitoring of blood from European citizens showed PFOA and PFOS levels in blood are decreasing, but levels of novel PFASs are increasing (EEA 2019). In 2009 EPA released an action plan on long-chain PFAS (including perfluoroalkyl sulfonates with six or more carbons (PFHxS and higher homologues) and perfluoroalkyl carboxylates with eight or more carbons (PFOA and high homologues), as well as their salts and precursors), noting long-chains are a concern for children's health, children have greater exposure than adults, and that "it can reasonably be anticipated that continued exposure could increase body burdens to levels that would result in adverse outcomes" (EPA 2009). The simplest endpoint of all PFASs within the perfluoroalkyl carboxylate family is trifluoroacetic acid (TFA), which is resistant to further degradation, miscible in water, not metabolized in mammalian systems, and can cause liver effects (Boutonnet et al. 2011). Though health-based toxicological effects vary for individual PFASs in humans or animals, the range of different types of effects for PFASs as a family combined with the similarity of effects for multiple perfluoroalkyl carboxylates and perfluoroalkyl sulfonates warrants attention to and reporting of the whole family of PFASs under the TRI.

[3] Polyfluoroalkyl substances (precursors) are known to break down or transform to perfluoroalkyl substances (such as perfluoroalkyl carboxylates and perfluoroalkyl sulfonates) due to natural and/or anthropogenically induced industrial, environmental, or metabolic conditions (Buck et al. 2011; CONCAWE 2016). Perfluoroalkyl carboxylates are the terminal degradation (biotic and abiotic) product for numerous families of polyfluoroalkyl substances (Buck et al. 2011). Polyfluoroalkyl substances represent, at a minimum, the same toxicological threat as the endpoint perfluoroalkyl substances which they may degrade or transform in to. ATSDR summarized relevant research for the perfluoroalkyls they evaluated; human exposure may occur from all contaminated media (air, water, soil, and food), they are very stable in the environment, are persistent in soil and leach into groundwater, and have been detected in oceans and the Arctic, demonstrating the potential for long-range transport (ATSDR 2018). PFASs that have been found in the environment include all the

routinely analyzed perfluoroalkyl carboxylates and perfluoroalkyl sulfonates previously discussed, as well as numerous replacement PFASs which are not routinely analyzed.

[4] [Insert]

[5] Analytical techniques (non-targeted and non-routine analysis) have been developed to aid in identification of the presence and chemical formula of unknown PFASs, however the lack of available standards for these chemicals limits the ability to quantitate the chemicals based on currently promulgated analytical methods. PFASs which are able to transform to perfluoroalkyls (precursors) in the environment are quantified using a commercially developed method, the Total Oxidizable Precursor Assay (Buechler 2017). Other commercial techniques have been developed which are able to quantitatively report total organofluorine, a proxy of total PFASs (Eurofins 2018).

[6] [Insert]

[7] [Insert]

[8] PFASs that have been found in humans, or which have had health-based advisory values or standards set for drinking water, include all of the routinely analyzed perfluoroalkyl carboxylates (four to fourteen carbons; PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnA, PFDoA, PFTrDA, PFTeDA), all of the routinely analyzed perfluoroalkyl sulfonates (four to ten carbons; PFBS, PFPeS, PFHxS, PFHpS, PFOS, PFNS, PFDS), other PFASs which are routinely analyzed but may transform to perfluoroalkyl substances (FOSA, 6:2 FTS, 8:2 FTS, GenX, N-MeFOSAA, N-EtFOSAA) and numerous other chemicals which are not, or are newly, routinely analyzed, including both perfluoroalkyl (perfluoroalkyl carboxylates (sixteen and eighteen carbons; PFHxDA and PFOcDA) and perfluoroalkyl phosphinic acids (PFPiAs)) and polyfluoroalkyl substances (polyfluoroalkyl phosphoric diesters (diPAPs), fluorotelomer alcohols (FTOH), fluorotelomer unsaturated carboxylic acids (FTUCAs; 6:2, 8:2, and 10:2), fluorotelomer carboxylic acids (FTCAs; 5:3 and 7:3) and perfluoroalkyl sulfonate derivatives – Cl-PFOS, Cl-PFHxS, ketone-PFOS, ether-PFHxS) (ITRC 2020; ATSDR 2018; CA 2015; EPA 2009).

[9] [Insert]

[10] EPA's validated Method 533 (December 2019) focuses on short chain PFASs and complements EPA Method 537.1 (November 2018). Using both methods, a total of 29 unique PFASs can be effectively measured in drinking water, including PFBS, PFPeS, PFHxS , PFHpS, PFOS, PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnA, PFDoA, PFTrDA, PFTeDA, 11Cl-PF3OUdS, 9Cl-PF3ONS, ADONA, HFPO-DA (GenX), 4:2FTS, 6:2FTS, 8:2FTS, NFDHA, PFEESA, PFMBA, PFMPA, NEtFOSAA, and NMeFOSAA (EPA 2019a).

[11] EPA 2020. See https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri

[12] EPA 2020. See https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri

[13] A maximum contaminant level (MCL) is the maximum concentration of a chemical in drinking water and has the force of law under the federal Safe Drinking Water Act. The federal MCL for PCBs is 500 parts per trillion (ppt). No federal MCLs have been set for PFASs, but a health advisory (HA) for PFOA/PFOS of 70 ppt has been established by EPA for drinking water. A HA is analogous to a MCL. A HA is also the maximum concentration of a chemical in drinking water, but, unlike a MCL it is only advisory; it does not have the force of law. The 70 ppt HA for PFOA/PFOS is roughly an order of magnitude lower than the 500 ppt MCL for PCBs, justifying setting a reporting threshold

for PFASs at one-pound, roughly an order of magnitude lower than the ten-pound reporting threshold for PCBs.

[14] ATSDR derived a health-based screening level of 0.02 µg/kg/day for total PCBs and has proposed draft health-based screening levels for four individual PFASs (PFOA, PFOS, PFNA and PFHxS) (ATSDR 2000, ATSDR 2018).

References

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EPA 2009 – Long-Chain Perfluorinated Chemicals (PFCs) Action Plan

Buck et al. 2011

CONCAWE 2016 – Environmental Fate and effects of PFASs

Buechler 2017 – Closing the PFAS Mass Balance: The Total Oxidizable Precursors (TOP) Assay)

Eurofins 2018 – EnviroNote No. 1080 – October 2018

ITRC 2020 - ITRC Table 4

CA 2015

ATSDR 2000 – Tox report for PCBs

EPA 2019a - See https://www.epa.gov/sites/production/files/2019-12/documents/table_of_pfas_methods_533_and_537.1.pdf

EPA 2020. See https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–TRI–2019–0375; FRL–10002–70]

RIN 2070–AK51

Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In this advance notice of proposed rulemaking (ANPRM), EPA is soliciting information from the public as EPA considers proposing a future rule on adding certain per- and polyfluoroalkyl substances (PFAS) to the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and section 6607 of the Pollution Prevention Act (PPA). In this ANPRM, EPA outlines what PFAS are, why the Agency is considering adding certain PFAS to EPCRA section 313, what listing actions are being considered, who may be required to report, the current understanding of hazard concerns for PFAS, EPA's hazard assessments on PFAS, and other information available on these chemicals. In considering a chemical for addition to the EPCRA section 313 list, EPA bases its listing decision on the chemical's hazard (*i.e.*, toxicity), not the risk (*i.e.*, toxicity plus potential exposures) related to that chemical. EPA is requesting comment on which, if any, PFAS should be evaluated for listing, how to list them, and what would be appropriate reporting thresholds given their persistence and bioaccumulation potential. Lastly, EPA asks for any additional data to inform the Agency's evaluation and determination of which PFAS may meet the EPCRA section 313 listing criteria.

DATES: Comments must be received on or before February 3, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–TRI–2019–0375, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/where-send-comments-epa-dockets#hq.*

All documents in the docket are listed on *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Daniel R. Bushman, Toxics Release Inventory Program Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0743; email: *bushman.daniel@epa.gov.*

For general information contact: The Emergency Planning and Community Right-to-Know Hotline; telephone numbers: toll free at (800) 424–9346 (select menu option 3) or (703) 348–5070 in the Washington, DC Area and International; or go to *https://www.epa.gov/home/epa-hotlines.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or otherwise use PFAS. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Facilities included in the following NAICS manufacturing codes (corresponding to Standard Industrial Classification (SIC) codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 211130*, 212324*, 212325*, 212393*, 212399*, 488390*, 511110, 511120, 511130, 511140*, 511191, 511199, 512230*, 512250*, 519130*, 541713*, 541715* or 811490*. *Exceptions and/or limitations exist for these NAICS codes.
- Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 212111, 212112, 212113 (corresponds to SIC code 12, Coal Mining (except 1241)); or 212221, 212222, 212230, 212299 (corresponds to SIC code 10, Metal Mining (except 1011, 1081, and 1094)); or 221111, 221112, 221113, 221118, 221121, 221122, 221330 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (corresponds to SIC codes 4911, 4931, and 4939, Electric Utilities); or 424690, 425110, 425120 (limited to facilities previously classified in SIC code 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 424710 (corresponds to SIC code 5171, Petroleum Bulk Terminals and Plants); or 562112 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC code 7389, Business Services, NEC)); or 562211, 562212, 562213, 562219, 562920 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 *et seq.*) (corresponds to SIC code 4953, Refuse Systems).
- Federal facilities.

A more detailed description of the types of facilities covered by the NAICS codes subject to reporting under EPCRA section 313 can be found at: *https://www.epa.gov/toxics-release-inventory-tri-program/tri-covered-industry-sectors.* To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372, subpart B of Title 40 of the Code of Federal Regulations. Federal facilities are required to report under Executive Order 13834 (*https://www.govinfo.gov/content/pkg/FR-2018-05-22/pdf/2018-11101.pdf*) as explained in the Implementing Instructions from the Council on Environmental Quality (*https://www.sustainability.gov/pdfs/eo13834_instructions.pdf*). If you have

questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. What action is under consideration by the Agency?

EPA is considering proposing a rule to add certain PFAS to the list of toxic chemicals subject to reporting under EPCRA section 313 and section 6607 of the PPA (more commonly known as the Toxics Release Inventory (TRI)). EPA is also considering establishing reporting thresholds for PFAS that are lower than the usual statutory thresholds (25,000 pounds for manufacturing or processing and 10,000 pounds for otherwise using listed chemicals) due to concerns for their environmental persistence and bioaccumulation potential.

C. What is the Agency's authority for this potential action?

This action is issued under EPCRA sections 313(d) and 328, 42 U.S.C. 11023 *et seq.*, and PPA section 6607, 42 U.S.C. 13106. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986.

Section 313 of EPCRA, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually to EPA and the States. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA, 42 U.S.C. 13106. Congress established an initial list of toxic chemicals that was comprised of 308 individually listed chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that EPA may add a chemical to the list if any of the listing criteria in EPCRA section 313(d)(2) are met. Therefore, to add a chemical, EPA must demonstrate that at least one criterion has been met, but need not determine whether any other criterion has been met. Conversely, to remove a chemical from the list, EPCRA section 313(d)(3) dictates that EPA must demonstrate that none of the criteria in ECPRA section 313(d)(2) have been met. The listing criteria in EPCRA section 313(d)(2)(A) through (C) are as follows:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
- The chemical is known to cause or can reasonably be anticipated to cause in humans: Cancer or teratogenic effects, or serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects.
- The chemical is known to cause or can be reasonably anticipated to cause, because of its toxicity, its toxicity and persistence in the environment, or its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA often refers to the EPCRA section 313(d)(2)(A) criterion as the "acute human health effects criterion;" the EPCRA section 313(d)(2)(B) criterion as the "chronic human health effects criterion;" and the EPCRA section 313(d)(2)(C) criterion as the "environmental effects criterion."

In a final rule that added 286 chemicals and chemical categories to the TRI list, EPA published in the **Federal Register** of November 30, 1994 (59 FR 61432) (FRL–4922–2), a statement clarifying its interpretation of the EPCRA section 313(d)(2) criteria for modifying the EPCRA section 313 list of toxic chemicals. EPA's interpretation of the EPCRA section 313 listing criteria addressed a number of issues including EPA's authority to add chemical categories and EPA's policy on the use of exposure for chemicals that are toxic only at high doses/concentrations.

II. Background Information

A. What is TRI?

EPCRA section 313, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to Pollution Prevention Act section 6607, 42 U.S.C. 13106. Note that TRI does not cover all chemicals, facilities, or types of pollution.

TRI provides information about releases of toxic chemicals from covered facilities throughout the United States; however, TRI data do not reveal whether or to what degree the public is exposed to listed chemicals. TRI data can, in conjunction with other information, be used as a starting point in evaluating such exposures and the risks posed by such exposures. The determination of potential risk to human health and/or the environment depends upon many factors, including the toxicity of the chemical, the fate of the chemical in the environment, and the amount and duration of human or other exposure to the chemical.

For more information on TRI, visit the TRI website at *www.epa.gov/tri.* Additionally, via this website, EPA provides a *Factors to Consider When Using TRI Data document,* which helps explain some of the uses, as well as limitations, of data collected by TRI.

B. What are PFAS?

PFAS are synthetic organic compounds that do not occur naturally in the environment. PFAS contain an alkyl carbon chain on which the hydrogen atoms have been partially or completely replaced by fluorine atoms. The strong carbon-fluorine bonds of PFAS make them resistant to degradation and thus highly persistent in the environment (Refs. 1 and 2). Some of these chemicals have been used for decades in a wide variety of consumer and industrial products (Ref. 1). Some PFAS have been detected at high levels in wildlife indicating that at least some PFAS have the ability to bioaccumulate (Ref. 2). Some PFAS can accumulate in humans and remain in the human body for long periods of time (*e.g.,* months to years) (Refs. 1, 2, and 3). As noted in EPA's Action Plan (Ref. 1), because of the widespread use of PFAS in commerce and their tendency to persist in the environment, most people in the United States have been exposed to PFAS. As a result, several PFAS have been detected in human blood serum (Refs. 1, 2 and 4).

C. Why is EPA considering adding PFAS to the TRI?

Some PFAS may be toxic, persistent in the environment, and accumulate in wildlife and humans. Therefore, releases of some PFAS to the environment and potential human exposure may be of concern. One source of potential exposure to PFAS are releases from industrial facilities that manufacture, process, or otherwise use PFAS. Information on the releases and waste management quantities from such facilities could help EPA and the public identify some potential sources of exposure to PFAS. The TRI is a tool that EPA can use to collect such information. As noted in the EPA Action Plan:

"Currently, no PFAS chemicals are included on the list of chemicals required to report to TRI; however, the EPA is considering whether to add

PFAS chemicals. In considering listing, the EPA must determine whether data and information are available to fulfill the listing criteria and the extent and utility of the data that would be gathered. For example, hazard data required for TRI listing may be readily available for certain PFAS chemicals, but not others. In addition, in considering if TRI will provide useful information to stakeholders, the EPA also will consider if those PFAS are still active in commerce. The process for listing includes notice and comment rulemaking to list PFAS chemicals for reporting prior to adding these chemicals to the TRI for annual reporting." (Ref. 1)

As the first step in the process of adding certain PFAS to the TRI, EPA is issuing this ANPRM to allow all stakeholders the opportunity to comment on the various aspects of adding certain PFAS to the TRI toxic chemical list. Note that adding certain PFAS to the TRI could help inform discussions related to risks to human health and the environment but the information collected through TRI, as previously indicated, would not capture all sources of PFAS releases.

III. What TRI listing actions are being considered?

Currently, approximately 600 PFAS are manufactured (including imported) and/or used in the United States (Ref. 5). The two PFAS that have been studied the most are perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Due to a voluntary phaseout under the 2010/2015 PFOA Stewardship Program, PFOA and PFOS are no longer produced domestically by the companies participating in the Program. However, PFOA and PFOS may still be produced domestically, imported, and used by companies not participating in the PFOA Stewardship Program (Ref. 6). PFOA and PFOS may also be present in imported articles. PFAS such as hexafluoropropylene oxide (HFPO) dimer acid (Chemical Abstract Service Registry Number (CASRN) 13252–13–6) and its ammonium salt (CASRN 62037–80–3), both commonly referred to as GenX, and perfluorobutane sulfonic acid (PFBS) (CASRN 375–73–5) and its salt potassium perfluorobutane sulfonate (CASRN 29420–49–3)), are some examples of short-chain PFAS that have been developed to replace long-chain PFOA and PFOS, respectively. Compared to PFOA and PFOS, most replacement PFAS tend to have less information available about their potential toxicity to human and ecological populations. Through this ANPRM process, EPA is seeking information to determine which PFAS currently active in commerce have sufficient toxicity information available to meet the EPCRA section 313(d)(2) listing criteria. EPA is considering whether to add any PFAS currently active in commerce for which hazard assessments show that they meet the EPCRA section 313(d)(2) listing criteria. Note that one factor EPA considers when determining whether to add a chemical to the TRI list is whether reporting would occur on the chemical if it were to be added.

In addition, for any PFAS that meet the listing criteria, EPA is considering adding these compounds to the list of chemicals of special concern (§ 372.28) and establishing lower reporting thresholds. In the past EPA has lowered the reporting thresholds for persistent, bioaccumulative, and toxic (PBT) chemicals (October 29, 1999, 64 FR 58666 (FRL–6389–11)). For PBT chemicals, with one exception, EPA established two reporting thresholds, 100 pounds for PBT chemicals and 10 pounds for highly PBT chemicals (*i.e.*, those PBT chemicals with very high persistence and bioaccumulation values). Certain PFAS may have persistence and bioaccumulation properties similar to other PBT chemicals where even small amounts of release present a concern. To appropriately capture release information of PFAS, EPA is considering establishing reporting thresholds lower than the statutory thresholds of 25,000 pounds for manufacturing or processing and 10,000 pounds for otherwise using listed chemicals.

PFAS, that meet the ECPRA section 313 listing criteria, could be listed as individual chemicals or as members of PFAS chemical categories. For example, EPA's "Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)" (Ref. 7) states that PFOS (CASRN 1763–23–1) is commonly produced as a potassium salt (CASRN 2795–39–3) and that, while the CASRN given is for linear PFOS, the toxicity studies are commonly based on a mixture of linear and branched PFOS. Therefore, the reference dose (RfD) derived in the 2016 Health Effects Support Document applies to the total linear and branched PFOS. For PFOS it would seem appropriate to create a TRI chemical category that includes all linear and branched isomers of PFOS and any salts of PFOS. PFOA has similar considerations, as may other PFAS that may warrant reporting as a category rather than as individually listed chemicals. EPA may also consider establishing a single chemical category for all PFAS, however, a single category would be of limited use since it would not provide any information about which PFAS are being released and/or managed as waste.

IV. What are the hazard concerns for PFAS?

Some PFAS are known to persist in the environment because they are resistant to degradation and have been shown to bioaccumulate in wildlife and humans (Refs. 1 and 2). There are also concerns that some PFAS may cause adverse human health effects, including reproductive, developmental, cancer, liver, immune, thyroid, and other effects (Refs. 1, 2, 8, and 9).

Based on their physicochemical properties and measured environmental concentrations, some PFAS are considered to be environmentally persistent chemicals (Refs. 1 and 2). In general, most PFAS are resistant to environmental degradation due to their strong carbon-fluorine bonds (Refs. 1 and 2). While PFAS chain length and chemical structure can have implications for environmental fate, PFAS are typically resistant to biodegradation, photooxidation, direct photolysis, and hydrolysis which is consistent with their persistence in soil and water (Ref. 2). Some PFAS, can also degrade or be metabolized to other PFAS such as PFOA or PFOS (Ref. 2). PFAS have been detected in air, surface water, groundwater, drinking water, soil, and food (Ref. 2). The presence of PFAS in many parts of the world, including the Arctic, indicate that long-range transport is possible (Ref. 2).

Under the TRI, bioaccumulation, to the extent it happens, is part of the hazard concerns and will be considered both in the listing criteria and in considering lower reporting thresholds. Bioconcentration factors (BCFs) estimated from an octanol-water partition coefficient (K_{ow}) or measured in aquatic tests, have typically been used to assess bioaccumulation potential. K_{ow} and the associated BCFs are based on the partitioning of organic chemicals into octanol or lipids. However, for PFAS such as PFOA and PFOS partitioning appears to be more related to their protein binding properties than to their lipophilicity (Refs. 8 and 9). Since K_{ow} does not provide a reliable estimate of bioaccumulation potential for these chemicals, field evidence of bioaccumulation is preferable. Field measured bioaccumulation factors (BAFs), and biomagnification factors (BMFs) or trophic magnification factors (TMFs) are considered more appropriate

indicators of the potential for PFAS, such as PFOA and PFOS, to accumulate in fish, other wildlife, and humans (Refs. 8, 9, 10, and 11). The trophic magnification data for PFOA and PFOS was deemed sufficient to consider them to be bioaccumulative by the Stockholm Convention Persistent Organic Pollutants Review Committee in 2015 (Ref. 12).

While the toxicity of PFOA and PFOS has been studied extensively, there is less data available for other PFAS (Ref. 2). Differences in PFAS chain length and chemical structure can have implications for environmental fate, bioaccumulation, metabolism, and toxicity (Ref. 1). As part of EPA's PFAS Action Plan, the Agency is continuing to collect, systematically review, and evaluate available toxicity data for other PFAS that may help determine whether exposure to structurally similar PFAS results in similar toxic effects (Ref. 1).

V. What EPA hazard assessments and other toxicity data are available for PFAS?

To date EPA has published two assessments of PFAS: (1) Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) and (2) Health Effects Support Document for Perfluorooctanoic Acid (PFOA) (Refs. 7 and 13). These two documents could be used to determine whether PFOA, PFOS, and related chemicals (*e.g.*, their salts) meet the EPCRA section 313(d)(2) listing criteria. EPA has also developed two new draft PFAS assessments for public comment: (1) Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252–13–6 and CASRN 62037–80–3) Also Known as "GenX Chemicals" and (2) Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375–73–5) and Related Compound Potassium Perfluorobutane Sulfonate (PFBS) (CASRN 29420–49–3) (Refs. 14 and 15). Once these documents are finalized, EPA expects these assessments will provide a basis for determining whether GenX chemicals and PFBS meet the EPCRA section 313(d)(2) listing criteria.

In addition, EPA is working on hazard assessments for the following PFAS containing varying degrees of available toxicity information relevant for human health assessment purposes: Perfluorononanoic acid (PFNA), perfluorobutanoic acid (PFBA), perfluorodecanoic acid (PFDA), perfluorohexanoic acid (PFHxA), and perfluorohexane sulfonic acid (PFHxS) (Ref. 16). Once finalized, EPA expects these assessments will provide a basis for determining whether these chemicals meet the EPCRA section 313(d)(2) listing criteria.

EPA has also collected scientific literature on approximately 30 PFAS. This list of PFAS and the available scientific literature is posted at *https://hero.epa.gov/hero/index.cfm/litbrowser/public/#PFAS*. For some of these PFAS, there may be epidemiological and/or experimental animal toxicity data available for review and evaluation of suitability to inform potential human health effects.

Lastly, EPA is collaborating with the National Toxicology Program (NTP) to study individual PFAS and PFAS as a chemical class. Specifically, the NTP has conducted toxicology studies to evaluate and identify the adverse effects of certain PFAS chemicals including PFBS, PFHxS, PFOS, PFHxA, PFOA, PFNA, and PFDA (*https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm*). NTP continues to assess the potential health effects of PFAS through a large multi-faceted research effort (*https://ntp.niehs.nih.gov/results/areas/pfas/index.html*).

The Agency relies on EPA hazard assessments and externally peer-reviewed hazard assessments from other federal agencies in making determinations as to whether a chemical meets the EPCRA section 313 listing criteria. EPA will consider all PFAS assessments on the human health and environmental effects of PFAS that are available from all sources, including those being conducted by other federal agencies.

VI. What information is EPA requesting?

EPA is seeking comments on which of the approximately 600 PFAS currently active in U.S. commerce the Agency should consider evaluating for potential addition to the EPCRA section 313 list of toxic chemicals. EPA would also like to receive comments on whether there are data available to inform how to list PFAS, *i.e.*, as individual chemical listings, as a single category, as multiple categories or as a combination of individual listings and category listings. Note that when chemicals are listed as a category, the TRI reports submitted would include combined data for all members of the category, such that there are no data reported specific to any individual member of the category.

EPA is also seeking comments on the appropriate reporting thresholds for PFAS. Reporting thresholds should be set at an appropriate level to capture most of the releases of PFAS from the facilities that submit reports under EPCRA section 313. Finally, EPA would like to receive any additional information on human health and environmental toxicity, persistence, and bioaccumulation of PFAS that would help determine if they meet the EPCRA section 313 listing criteria.

VII. What are the next steps EPA will take?

EPA intends to carefully review all the comments and information received in response to this ANPRM, as well as previously collected and assembled studies. Once that review is completed, EPA may supplement the collected information with additional hazard assessments to determine whether some PFAS meet the EPCRA section 313(d)(2) criteria. Should EPA decide to move forward with this action, the next step will be to publish a proposed rule to add certain PFAS to the EPCRA section 313 toxic chemical list and set the appropriate reporting thresholds. At that time, the public will have the opportunity to comment on EPA's proposal.

VIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA. EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan. EPA 823R18004. U.S. Environmental Protection Agency, Washington, DC. February 2019. Available from: *https://www.epa.gov/pfas/epas-pfas-action-plan*.
2. ATSDR. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Perfluoroalkyls—Draft for Public Comment. June 2018. Available from: *https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf*.
3. USEPA. Basic Information on PFAS. U.S. Environmental Protection Agency, Washington, DC. Available from: *https://www.epa.gov/pfas/basic-information-pfas*.
4. Department of Health and Human Services, Centers for Disease Control and Prevention. Fourth National Report on Human Exposure to Environmental Chemicals. Pages 247–257, 2009. Available from: *https://www.cdc.gov/exposurereport/pdf/fourthreport.pdf*.
5. USEPA. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. U.S. Environmental Protection Agency, Washington, DC. Available from: *https://www.epa.gov/tsca-inventory*.

6. USEPA. Fact Sheet: 2010/2015 PFOA Stewardship Program. Available from: *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program.*
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10. USEPA. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) Technical Support Document Volume 2: Development of National Bioaccumulation Factors. Office of Water, Office of Science and Technology. December 2003 (EPA–822–R–03–030). Available from: *https://www.epa.gov/sites/production/files/2018-10/documents/methodology-wqc-protection-hh-2000-volume2.pdf.*
11. Gobas, F.A.P.C., Watze de Wolf, W., Burkhard, L.P., Verbruggen, E., I and Plotzke, K. 2009. Revisiting Bioaccumulation Criteria for POPs and PBT Assessments. Integrated Environmental Assessment and Management—Volume 5, Number 4—pp. 624–637.
12. UNEP. Proposal to list pentadecafluorooctanoic acid (CAS No: 335–67–1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants. United Nations Environmental Program. 2015. Available from: *http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC11/POPRC11Documents/tabid/4573/.*
13. USEPA. Health Effects Support Document for Perfluorooctanoic Acid (PFOA). EPA 822–R–16–003. U.S. Environmental Protection Agency, Washington, DC. May 2016. Available from: *https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*
14. USEPA. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252–13–6 and CASRN 62037–80–3) Also Known as "GenX Chemicals. Public Comment Draft. EPA–823–P–18–001. U.S. Environmental Protection Agency, Washington, DC. November 2018. Available from: *https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf.*
15. USEPA. Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375–73–5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420–49–3). Public Comment Draft. EPA–823–R–18–307. U.S. Environmental Protection Agency, Washington, DC. November 2018. Available from: *https://www.epa.gov/sites/production/files/2018-11/documents/pfbs_public_comment_draft_toxicity_assessment_nov2018-508.pdf.*
16. USEPA. IRIS Program Outlook. A Message from the IRIS Program (April 2019). U.S. Environmental Protection Agency, Washington, DC. Available from: *https://www.epa.gov/sites/production/files/2019-04/documents/iris_program_outlook_apr2019.pdf.*

IX. Statutory and Executive Order Reviews

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Any changes made in response to OMB recommendations have been documented in the docket for this action. Because this action does not propose or impose any requirements, and instead seeks comments and suggestions for the Agency to consider in possibly developing a subsequent proposed rule, the various statutes and Executive Orders that normally apply to rulemaking do not apply in this case. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Orders as applicable to that rulemaking.

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: November 25, 2019.

Andrew R. Wheeler,

Administrator.

[FR Doc. 2019–26034 Filed 12–3–19; 8:45 am]

BILLING CODE 6560–50–P

McDougall, Robert

From: Bereket Tesfu <btesfu@naag.org>
Sent: Tuesday, January 28, 2020 1:54 PM
Subject: RE: [PFAS ACTION ITEM] *January 2* NAAG national environmental conference call
Attachments: 2020 01 22 Comments_ANPR PFAS TRI (draft).docx; ANPRM.pdf

Importance: High

EXTERNAL SENDER: Do not open attachments or click on links unless you recognize and trust the sender.
Just one last reminder, the deadline for signatures is tomorrow (Wednesday, January 29).

Bereket Tesfu
Program Counsel

National Attorneys General Training & Research Institute
National Association of Attorneys General
1850 M Street NW, 12th Floor
Washington, DC 20036
(202) 326-6269 | btesfu@naag.org

From: Bereket Tesfu
Sent: Wednesday, January 22, 2020 5:23 PM
To: Bereket Tesfu <btesfu@naag.org>
Subject: RE: [PFAS ACTION ITEM] *January 2* NAAG national environmental conference call
Importance: High

Hello, all. Following up on the e-mail below and the subsequent January conference call, attached is the much-anticipated draft letter from the New York Attorney General's office pertaining to comments on adding PFASs to the Toxics Release Inventory (TRI). (Also attached is the EPA's advanced notice of proposed rulemaking.) Here is a note from Philip Bein pertaining to the attached draft letter:

"Attached is the NYAG's draft for the comment letter on adding PFASs to the Toxics Release Inventory. When you distribute please inform the other AG offices that the end notes are incomplete and we are still working on them. We would like to receive any comments on the draft and sign on by January 29."

Because the EPA deadline to submit comments is **February 3**, and it took longer than expected to put the draft letter together, *time is of the essence* from here on out to meet New York's internal deadline of **January 29** for signatures.

If another conference call is necessary between now and January 29 to discuss the draft letter, I'm more than happy to facilitate that. Please let me know.

If anyone wants to directly reach Philip Bein, he can be contacted at Philip.Bein@ag.ny.gov.

If you
Bereket Tesfu
Program Counsel

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National Association of Attorneys General
1850 M Street NW, 12th Floor
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(202) 326-6269 | btesfu@naag.org

From: Bereket Tesfu
Sent: Monday, December 30, 2019 12:19 PM
Subject: [PFAS ACTION ITEM] *January 2* NAAG national environmental conference call
Importance: High

Hello, everyone. I hope you've been enjoying the holidays. An imminent PFAS action item has arisen that can be addressed on the call this week.

I received the following message from the New York Attorney General's Office:

"State Comments on Rulemaking for Inclusion of PFAS in Toxics Release Inventory

On December 3, 2019, EPA published an advance notice of proposed rulemaking (ANPRM) soliciting comments from the public concerning a possible future rule that would add PFAS to the toxics release inventory (TRI), the list of toxic chemicals subject to reporting under Section 313 of the Emergency Planning and Community Right-to- Know Act (EPCRA). A copy of the ANPRM is attached. In addition, the National Defense Authorization Act for Fiscal Year 2020 (NDAA) was passed just days ago. It amends EPCRA by adding various PFAS chemicals to the TRI and by providing for assessment of other PFAS for possible future inclusion. New York believes that the NDAA is an important step forward in including PFAS chemicals on the list so that releases of such chemicals by facilities can be tracked and

reported. However, the State believes that the entire class of PFAS chemicals should be included in the TRI. New York is developing comments proposing to add that class to the TRI and wants to solicit other states to join in these comments."

The Federal Register advanced notice is attached to this e-mail. **Comments are due by February 3, 2020**, so the call this week may be the last reasonable opportunity to have as many states as possible in one forum to have a discussion on this issue and possibly coordinate from it.

If you have any other proposed agenda items, please send them my way.

To access the conference call on **January 2, 2020, at 1:00 p.m. (ET)**, call in to [redacted] and use the **pass code** [redacted] *The conference call will open with a roll call of states.* Once the substantive discussions begin, we ask that participants identify themselves by name and state so we can know who's speaking.

We kindly ask that this invitation or any information about this call not be forwarded to or shared with anyone beyond the attorney general community. This request is to ensure that those who participate on this call are only those who work on environmental matters for their respective attorney general offices. This conference call is not for industry, the press, or the general public.

We look forward to you joining us on January 2.

Bereket Tesfu
Program Counsel

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Attorneys General of the States of New York and [INSERT]

February 3, 2020

Via Regulations.gov and First Class Mail
Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

Re: Comments on the Advance Notice of Proposed Rulemaking, *Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting* (ANPRM), 84 Fed. Reg. 66369 (Dec. 4, 2019)

Docket ID No. EPA-HQ-TRI-2019-0375

Dear Administrator Wheeler:

In the ANPRM, the Environmental Protection Agency (EPA) requests comments "on which, if any, PFAS should be evaluated for listing [on the Toxics Release Inventory], how to list them, and what would be appropriate reporting thresholds given their persistence and bioaccumulation potential." 84 Fed. Reg. 66369 (Dec. 4, 2019). More specifically, EPA also seeks comments on "which of the approximately 600 PFAS currently active in U.S. commerce the Agency should consider evaluating for potential addition to the [Toxics Release Inventory]," and comments on "whether there are data available to inform how to list PFAS, *i.e.*, as individual chemical listings, as a single category, as multiple categories or as a combination of individual listings and category listings." 84 Fed. Reg. at 66373.

As discussed below, the state attorneys general respectfully submit these comments in support of a future rulemaking by EPA to list *per*-fluoroalkyl and *poly*-fluoroalkyl substances (PFASs) on the Toxics Release Inventory (TRI) as a combination of a single category listing for all PFASs and as individual listings for specific compounds in the category. As a family, the close chemical similarities between well-known PFASs and those in the entire chemical category indicates that any member of the family "can be reasonably anticipated to cause" acute and/or chronic harms to human health and adverse effects to the environment, for purposes of listing to the TRI Program. For a number of individual PFAS chemicals, considerable information is already known demonstrating the acute and chronic harms these chemicals pose to human health and their significant adverse effects to the environment. Reporting of these chemicals is feasible because validated and commonly-accepted methods exist to measure the levels of these PFASs in drinking water.

In addition, the attorneys general recommend that EPA set a TRI reporting threshold of one pound for both the PFAS category and individual PFAS chemicals as described below.

Background

PFASs

PFASs have been incorporated into countless consumer products since the 1940s, including textiles with Scotchgard, Teflon products, non-stick cookware, and food packaging. PFASs have also been used for decades as ingredients in firefighting foam used across the country, including by the U.S. military and local fire departments. As the ANPRM points out, PFASs risk harm to the environment and to human health, and numerous PFASs have been found in human blood. PFAS are known as "forever chemicals" because they resist degradation and are persistent in the environment. PFASs also bioaccumulate and are toxic to humans and animals. Although scientific knowledge regarding the toxicity of most PFASs is still developing, PFASs are linked to serious adverse health effects in humans and animals, including reproductive, developmental, cancer, liver, immune, thyroid, and other effects.

The Emergency Planning and Community Right-to-Know Act (1986) and the Pollution Prevention Act (1990)

The TRI Program provides an important system to keep the public and government agencies informed about toxic chemicals in our communities. Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) requires certain federal and industrial facilities that manufacture, process, or otherwise use chemicals listed in the TRI above threshold quantities to report, on an annual basis, the amounts of these chemicals released into the environment and otherwise managed as waste. EPCRA, 42 U.S.C. § 11023. Likewise, the Pollution Prevention Act (PPA) requires regulated facilities to report pollution prevention and recycling data for chemicals on the TRI. PPA, section 6607, 42 U.S.C. § 13106.

Congress created the TRI Program as part of its response to serious chemical releases in the 1980s from Union Carbide facilities in Bhopal, India, and Institute, West Virginia. Through EPCRA, and later, PPA, Congress sought to support and promote emergency planning and to provide the public with information about releases of toxic chemicals in their communities. The TRI Program serves an essential function by providing information to federal, state, and local governments about releases of toxic chemicals to the environment, incentivizing companies to improve their environmental performance, and aiding in the development of appropriate regulations, guidelines, and standards. 42 U.S.C. §11023(h).

Chemicals are included on the TRI by statutory inclusion by Congress, or by designation by EPA. The agency may add chemicals to the TRI under authority delegated to EPA pursuant to EPCRA based on evidence that a chemical is "known to cause or can be reasonably anticipated to cause" acute or chronic adverse human health effects or significant adverse environmental effects. 42 U.S.C. § 11023(d)(2).

The National Defense Authorization Act for Fiscal Year 2020 (NDAA)

In December of 2019, Congress amended EPCRA through certain provisions of the NDAA by adding certain individual PFAS chemicals to the TRI Program. NDAA, Pub. Law 116-92 (December 20, 2019). These include the PFASs commonly known as PFOA, PFOS, GenX, PFNA, and PFHxS, and certain salts and other compounds associated with these PFASs, along with other PFASs listed under other statutes and regulations. NDAA, section 7321(b)(1). The NDAA also amends EPCRA by establishing a reporting threshold for these PFASs of 100 pounds. *Id.*, section 7321(b)(2). As relevant to this ANPRM, the NDAA also provides for the possible future inclusion of other PFASs into the TRI Program. *Id.*, section 7321(c).

* * *

The undersigned attorneys general believe that the NDAA is an important first step in including PFAS chemicals on the TRI so that governments, communities, and regulated companies themselves can engage in informed decision-making about the lifecycles of such chemicals at covered facilities. As described below, the attorneys general urge EPA to now proceed with a rulemaking to cover the entire family of PFASs, along with certain individual PFAS chemicals, at a reporting threshold of one pound. Our recommendations here echo those in a July 2019 letter sent by twenty-two state attorneys general, including many of those undersigned, to United States Congressional leadership (July 30, 2019 Attorneys General Letter to Congress).[1] Among other things, the letter requested the addition of the entire family of PFASs to the TRI to help identify new potential sources and areas of contamination, at a very low reporting level. As intended by the TRI Program, the actions we recommend below will provide the public with necessary and critical information about releases of PFASs in their communities.

Recommendations

The state attorneys general respectfully make the following recommendations:

Recommendation 1:

Add all PFASs to the TRI Program as a single category listing.

The attorneys general respectfully recommend that EPA include all PFASs, as a class, to the TRI Program. Our recommendation applies to the entire category of PFASs, potentially consisting of more than 10,000 individual chemicals, rather than a more limited coverage of the approximately 600 PFASs the ANPRM states are presently deemed active in U.S. commerce. By casting a wider net, the TRI Program would account for PFASs that may not be purposefully manufactured for commercial use, but that are nevertheless constituents of commercial products. The class of PFASs satisfies EPCRA's listing criteria because they are "known to cause or can reasonably anticipated to cause" acute and/or chronic harm to human health and significant adverse effects to the environment. EPCRA, section 313(d)(2). For clarity, however, we take no position as to whether a maximum contaminant level (MCL) should be established under either federal law or the law of any state for PFASs, as a class, as listing to the TRI Program and the establishment of an MCL serve fundamentally different purposes and involve different criteria.

PFASs commonly analyzed and used in commerce in our states, including *per*-fluoroalkyl carboxylates (such as PFOA) and *per*-fluoroalkyl sulfonates (such as PFOS), can show similar indicia of toxicity, persistence in the environment, and tendency to accumulate ubiquitously in the environment and in biota.[2] Increasingly, industry is substituting *poly*-fluoroalkyl substances for *per*-fluoroalkyl substances, which have been used more traditionally in all manner of consumer products. However, *poly*-fluoroalkyl substances can readily break down or transform to both *per*-fluoroalkyl carboxylates and sulfonates whose toxicity, persistence, and bioaccumulation are well-known.[3] Ultra-short chain PFASs, *i.e.* those with a backbone of less than four carbon molecules, may pose a similar risk to human health and the environment. These PFASs may share similar characteristics with PFASs that are known to be toxic, persistent, and bioaccumulative, *e.g.*, a high degree of fluorination, lack of known degradation mechanism, confirmed environmental occurrence and reasonably assumed health-based toxicological endpoints.[4]

Commonly-used and widely-accepted commercial techniques are available to identify and quantify both short- and long-chain PFAS compounds. Likewise, total ultra-short PFAS concentrations can be readily estimated using a combination of commercially available analytical techniques.[5]

EPA has ample experience listing chemical families as a single category in the TRI Program. For example, the TRI lists all polychlorinated biphenyls (PCBs), a diverse family of compounds, as a single category. EPA has appropriately done so despite the chemical-specific differences in environmental fate and transport processes among individual PCBs as well as health-based impacts. PCBs provide an especially helpful example here as they tend to accumulate or demonstrate harm to humans and animals at many of the same health-based endpoints as PFASs, for example, liver, thyroid, immunological alterations, neurodevelopmental changes,

reduced birth weight, reproductive toxicity, and cancer.[6] Like many PFASs, PCBs are known to be persistent, bioaccumulative, and toxic.

Finally, the attorneys general recommend a chemical family-based approach for listing PFASs on the TRI as it will provide critical information to enable the states, other regulators, and facility operators to better understand the use and potential for release of PFASs from regulated facilities. As a result, existing and future waste streams containing PFASs can be appropriately managed, remediated, and regulated, and uncontrolled releases can better be prevented to avoid adverse impacts to public health and the environment. Moreover, the cost of expanding reporting requirements for PFASs can be offset by the benefits of reducing environmental releases of these chemicals. For example, fugitive emission abatement tends to pay for itself in recovered materials.

Recommendation 2:

Add all PFASs to the TRI Program as individual listings to the extent that: (1) for each PFAS listed, a method to measure its level in drinking water has been validated by the Administrator; and (2) the chemical is not already listed pursuant to the NDAA.

EPA also should simultaneously list a number of individual PFAS chemicals to the TRI Program. The toxicity of PFOA and PFOS, the most studied PFASs to date, to humans and the environment is well known.[7] The recently enacted NDAA added several of the commonly recognized PFAS chemicals to the TRI Program, including PFOA and PFOS, along with GenX, PFNA, and PFHxS, together with certain salts and other compounds associated with each of these, and other PFASs identified under other statutes and regulations. NDAA, section 7321(b)(1). The state attorneys general commend Congress on this important first step.

For purposes of listing in the TRI, a number of additional PFASs may be reasonably anticipated to share the same hallmarks of persistence, bioaccumulation, and/or toxicity to humans as those already added to the TRI Program through the NDAA, with similar health-based effects at comparable exposure endpoints.[8] Compared to PFASs with well-known human health and environmental impacts, these additional PFASs may also be anticipated to accumulate in the environment with wide-ranging contamination in air, water, solids and multiple biological tissues, and/or break down to other PFASs whose impacts are known.[9] Many of these chemicals are readily measurable in drinking water using validated methods.

These individual PFASs easily meet EPCRA's criteria for listing to the TRI Program. The attorneys general urge EPA to exercise its authority to close the remaining regulatory gap for these PFASs. Consistent with the approach

implemented by Congress under the NDAA, these individual PFASs should be listed, along with their salt forms and closely-related chemicals (*e.g.*, linear and branched isomers).[10]

Recommendation 3:

The TRI Threshold Reporting Limit should be one pound for both individual PFAS chemicals and for the PFAS chemical compound category.

EPCRA establishes reporting thresholds of 25,000 pounds for facilities involved in manufacturing or processing listed chemicals, and 10,000 pounds for facilities that otherwise use listed chemicals. As the ANPRM recognizes, however, in the past EPA has established lower reporting thresholds for listed chemicals of special concern. EPA has also lowered reporting thresholds for persistent, bioaccumulative, and toxic (PBT) chemicals and chemical compound categories, and in particular, for PBTs with very high persistence and bioaccumulation values. 84 Fed. Reg. at 66371.

As discussed above, PFASs are well-understood to be highly persistent and bioaccumulative chemicals. Consequently, EPA should add individually-listed PFASs and the compound category of PFASs to the list of chemicals of special concern, ECPRA, section 372.28, and, at minimum, set a reporting threshold of 10 pounds (*i.e.*, for highly PBT chemicals). However, given their high potential for causing acute and chronic harm to humans and biota, in addition to their high persistence and bioaccumulative tendencies, the state attorneys general recommend that EPA set a threshold reporting requirement of one pound for PFASs.

A lower reporting threshold for PFASs is not without precedent. EPA has lowered the threshold reporting requirements for 16 PBT chemicals and five PBT categories due to the insidious threats PBTs pose compared to other chemicals in the TRI Program.[11] Of these, EPA has set reporting thresholds of 10 pounds for 10 PBT chemicals and one PBT category. Going further, EPA lowered the reporting threshold for the PBT chemical compound category of Dioxin and Dioxin-Like Compounds, to one tenth of a gram (0.0002205 pounds).[12]

A reporting threshold of one pound for both individual PFAS chemicals and the chemical compound category of PFASs is appropriate and warranted. For PCBs, a category of 209 individual PBT chemical compounds, EPA established an updated TRI reporting threshold of 10 pounds in 1999. Federal drinking water limits established by EPA are an order of magnitude lower for PFASs than for PCBs. Applying the same ratio, the TRI reporting threshold for PFASs should be an order of magnitude lower than for PCBs, *i.e.* one pound.[13]

Work by the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR) also supports a one-pound reporting threshold for PFASs. ATSDR derived a health-based screening level for total PCBs and has proposed draft health-based screening levels for four individual PFASs which are at or an order of magnitude lower than the health-based screening levels previously established for PCBs.[14] This justifies setting a reporting threshold for PFASs at one pound, roughly an order of magnitude lower than the ten-pound reporting threshold for PCBs.

Conclusion

The attorneys general appreciate this opportunity to comment on this ANPRM, and look forward to a future rulemaking that incorporates the recommendations set forth herein.

Sincerely,

[INSERT SIGNATURE BLOCKS]

End Notes

[1] July 30, 2019 Letter of State Attorneys General, *available at*: [https://ag.ny.gov/sites/default/files/multistate_pfas_legislative_letter_7.30.19_final.pdf].

[2] Comparison of toxicity for perfluoroalkyl substances is complicated due to limited studies, differences between genders, across species, and in mechanism of endpoint for specific chemicals, however, similarities exist in terms of association of specific health risks to multiple chemicals within the PFASs family. Suggested associations in humans include pregnancy-induced hypertension (PFOA and PFOS), hepatic effects (PFOA, PFOS and PFHxS), cholesterol effects (PFOA, PFOS, PNFA and PFDA), thyroid disease (PFOA and PFOS), antibody response (PFOA, PFOS, PFHxS and PFDA), asthma (PFOA), developmental effects (PFOA and PFOS) and death (PFOA and PFOS) (ATSDR 2018). Multiple replacement PFASs (6:2 chlorinated polyfluorinated ether sulfonate (6:2 Cl-PFESA), HFPO trimer acid (HFPO-TA), HFPO tetramer acid (HFPO-TeA), and 6:2 fluorotelomer sulfonic acid (6:2 FTS)) have been shown to have greater toxic effects on the human liver HL-7702 cell line, as compared to PFOA and PFOS (Sheng et al. 2018a).

ATSDR reviewed 187 animal studies and found that primary effects from exposure to perfluoroalkyl substances included hepatic (PFOA, PFOS, PFBA, PFHxA, PFHpA, PFNA, PFDA, PFUnA, PFDoA, PFBS and PFHxS), developmental (PFOA, PFOS, PFBA, PFHxA, PFNA, PFDA, PFUnA, PFDoA and PFHxS), and immune toxicity (PFOA, PFOS), though not all effects were observed or examined for the fourteen PFASs ATSDR evaluated. Additional effects were also found in laboratory animals relating to the kidney (PFHxA, PFUnA, PFBS and PFHxS), thyroid functioning (PFBA and PFHxS), and death (PFHxA, PFNA and PFDA) (ATSDR 2018). Compared to PFOA, HFPO-TA showed greater liver toxicity and bioaccumulation potential in mice (Sheng et al. 2018b).

Human biomonitoring of blood from European citizens showed PFOA and PFOS levels in blood are decreasing, but levels of novel PFASs are increasing (EEA 2019). In 2009 EPA released an action plan on long-chain PFAS (including perfluoroalkyl sulfonates with six or more carbons (PFHxS and higher homologues) and perfluoroalkyl carboxylates with eight or more carbons (PFOA and high homologues), as well as their salts and precursors), noting long-chains are a concern for children's health, children have greater exposure than adults, and that "it can reasonably be anticipated that continued exposure could increase body burdens to levels that would result in adverse outcomes" (EPA 2009). The simplest endpoint of all PFASs within the perfluoroalkyl carboxylate family is trifluoroacetic acid (TFA), which is resistant to further degradation, miscible in water, not metabolized in mammalian systems, and can cause liver effects (Boutonnet et al. 2011). Though health-based toxicological effects vary for individual PFASs in humans or animals, the range of different types of effects for PFASs as a family combined with the similarity of effects for multiple perfluoroalkyl carboxylates and perfluoroalkyl sulfonates warrants attention to and reporting of the whole family of PFASs under the TRI.

[3] Polyfluoroalkyl substances (precursors) are known to break down or transform to perfluoroalkyl substances (such as perfluoroalkyl carboxylates and perfluoroalkyl sulfonates) due to natural and/or anthropogenically induced industrial, environmental, or metabolic conditions (Buck et al. 2011; CONCAWE 2016). Perfluoroalkyl carboxylates are the terminal degradation (biotic and abiotic) product for numerous families of polyfluoroalkyl substances (Buck et al. 2011). Polyfluoroalkyl substances represent, at a minimum, the same toxicological threat as the endpoint perfluoroalkyl substances which they may degrade or transform in to. ATSDR summarized relevant research for the perfluoroalkyls they evaluated; human exposure may occur from all contaminated media (air, water, soil, and food), they are very stable in the environment, are persistent in soil and leach into groundwater, and have been detected in oceans and the Arctic, demonstrating the potential for long-range transport (ATSDR 2018). PFASs that have been found in the environment include all the

routinely analyzed perfluoroalkyl carboxylates and perfluoroalkyl sulfonates previously discussed, as well as numerous replacement PFASs which are not routinely analyzed.

[4] [Insert]

[5] Analytical techniques (non-targeted and non-routine analysis) have been developed to aid in identification of the presence and chemical formula of unknown PFASs, however the lack of available standards for these chemicals limits the ability to quantitate the chemicals based on currently promulgated analytical methods. PFASs which are able to transform to perfluoroalkyls (precursors) in the environment are quantified using a commercially developed method, the Total Oxidizable Precursor Assay (Buechler 2017). Other commercial techniques have been developed which are able to quantitatively report total organofluorine, a proxy of total PFASs (Eurofins 2018).

[6] [Insert]

[7] [Insert]

[8] PFASs that have been found in humans, or which have had health-based advisory values or standards set for drinking water, include all of the routinely analyzed perfluoroalkyl carboxylates (four to fourteen carbons; PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnA, PFDoA, PFTrDA, PFTeDA), all of the routinely analyzed perfluoroalkyl sulfonates (four to ten carbons; PFBS, PFPeS, PFHxS, PFHpS, PFOS, PFNS, PFDS), other PFASs which are routinely analyzed but may transform to perfluoroalkyl substances (FOSA, 6:2 FTS, 8:2 FTS, GenX, N-MeFOSAA, N-EtFOSAA) and numerous other chemicals which are not, or are newly, routinely analyzed, including both perfluoroalkyl (perfluoroalkyl carboxylates (sixteen and eighteen carbons; PFHxDA and PFOcDA) and perfluoroalkyl phosphinic acids (PFPiAs)) and polyfluoroalkyl substances (polyfluoroalkyl phosphoric diesters (diPAPs), fluorotelomer alcohols (FTOH), fluorotelomer unsaturated carboxylic acids (FTUCAs; 6:2, 8:2, and 10:2), fluorotelomer carboxylic acids (FTCAs; 5:3 and 7:3) and perfluoroalkyl sulfonate derivatives – Cl-PFOS, Cl-PFHxS, ketone-PFOS, ether-PFHxS) (ITRC 2020; ATSDR 2018; CA 2015; EPA 2009).

[9] [Insert]

[10] EPA's validated Method 533 (December 2019) focuses on short chain PFASs and complements EPA Method 537.1 (November 2018). Using both methods, a total of 29 unique PFASs can be effectively measured in drinking water, including PFBS, PFPeS, PFHxS , PFHpS, PFOS, PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnA, PFDoA, PFTrDA, PFTeDA, 11Cl-PF3OUdS, 9Cl-PF3ONS, ADONA, HFPO-DA (GenX), 4:2FTS, 6:2FTS, 8:2FTS, NFDHA, PFEESA, PFMBA, PFMPA, NEtFOSAA, and NMeFOSAA (EPA 2019a).

[11] EPA 2020. See https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri

[12] EPA 2020. See https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri

[13] A maximum contaminant level (MCL) is the maximum concentration of a chemical in drinking water and has the force of law under the federal Safe Drinking Water Act. The federal MCL for PCBs is 500 parts per trillion (ppt). No federal MCLs have been set for PFASs, but a health advisory (HA) for PFOA/PFOS of 70 ppt has been established by EPA for drinking water. A HA is analogous to a MCL. A HA is also the maximum concentration of a chemical in drinking water, but, unlike a MCL it is only advisory; it does not have the force of law. The 70 ppt HA for PFOA/PFOS is roughly an order of magnitude lower than the 500 ppt MCL for PCBs, justifying setting a reporting threshold

for PFASs at one-pound, roughly an order of magnitude lower than the ten-pound reporting threshold for PCBs.

[14] ATSDR derived a health-based screening level of 0.02 µg/kg/day for total PCBs and has proposed draft health-based screening levels for four individual PFASs (PFOA, PFOS, PFNA and PFHxS) (ATSDR 2000, ATSDR 2018).

References

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EPA 2009 – Long-Chain Perfluorinated Chemicals (PFCs) Action Plan

Buck et al. 2011

CONCAWE 2016 – Environmental Fate and effects of PFASs

Buechler 2017 – Closing the PFAS Mass Balance: The Total Oxidizable Precursors (TOP) Assay)

Eurofins 2018 – EnviroNote No. 1080 – October 2018

ITRC 2020 - ITRC Table 4

CA 2015

ATSDR 2000 – Tox report for PCBs

EPA 2019a - See https://www.epa.gov/sites/production/files/2019-12/documents/table_of_pfas_methods_533_and_537.1.pdf

EPA 2020. See https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–TRI–2019–0375; FRL–10002–70]

RIN 2070–AK51

Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In this advance notice of proposed rulemaking (ANPRM), EPA is soliciting information from the public as EPA considers proposing a future rule on adding certain per- and polyfluoroalkyl substances (PFAS) to the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and section 6607 of the Pollution Prevention Act (PPA). In this ANPRM, EPA outlines what PFAS are, why the Agency is considering adding certain PFAS to EPCRA section 313, what listing actions are being considered, who may be required to report, the current understanding of hazard concerns for PFAS, EPA's hazard assessments on PFAS, and other information available on these chemicals. In considering a chemical for addition to the EPCRA section 313 list, EPA bases its listing decision on the chemical's hazard (*i.e.*, toxicity), not the risk (*i.e.*, toxicity plus potential exposures) related to that chemical. EPA is requesting comment on which, if any, PFAS should be evaluated for listing, how to list them, and what would be appropriate reporting thresholds given their persistence and bioaccumulation potential. Lastly, EPA asks for any additional data to inform the Agency's evaluation and determination of which PFAS may meet the EPCRA section 313 listing criteria.

DATES: Comments must be received on or before February 3, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–TRI–2019–0375, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/where-send-comments-epa-dockets#hq.*

All documents in the docket are listed on *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Daniel R. Bushman, Toxics Release Inventory Program Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0743; email: *bushman.daniel@epa.gov.*

For general information contact: The Emergency Planning and Community Right-to-Know Hotline; telephone numbers: toll free at (800) 424–9346 (select menu option 3) or (703) 348–5070 in the Washington, DC Area and International; or go to *https://www.epa.gov/home/epa-hotlines.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or otherwise use PFAS. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Facilities included in the following NAICS manufacturing codes (corresponding to Standard Industrial Classification (SIC) codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 211130*, 212324*, 212325*, 212393*, 212399*, 488390*, 511110, 511120, 511130, 511140*, 511191, 511199, 512230*, 512250*, 519130*, 541713*, 541715* or 811490*. *Exceptions and/or limitations exist for these NAICS codes.
- Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 212111, 212112, 212113 (corresponds to SIC code 12, Coal Mining (except 1241)); or 212221, 212222, 212230, 212299 (corresponds to SIC code 10, Metal Mining (except 1011, 1081, and 1094)); or 221111, 221112, 221113, 221118, 221121, 221122, 221330 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (corresponds to SIC codes 4911, 4931, and 4939, Electric Utilities); or 424690, 425110, 425120 (limited to facilities previously classified in SIC code 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 424710 (corresponds to SIC code 5171, Petroleum Bulk Terminals and Plants); or 562112 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC code 7389, Business Services, NEC)); or 562211, 562212, 562213, 562219, 562920 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 *et seq.*) (corresponds to SIC code 4953, Refuse Systems).
- Federal facilities.

A more detailed description of the types of facilities covered by the NAICS codes subject to reporting under EPCRA section 313 can be found at: *https://www.epa.gov/toxics-release-inventory-tri-program/tri-covered-industry-sectors.* To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372, subpart B of Title 40 of the Code of Federal Regulations. Federal facilities are required to report under Executive Order 13834 (*https://www.govinfo.gov/content/pkg/FR-2018-05-22/pdf/2018-11101.pdf*) as explained in the Implementing Instructions from the Council on Environmental Quality (*https://www.sustainability.gov/pdfs/eo13834_instructions.pdf*). If you have

questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. What action is under consideration by the Agency?

EPA is considering proposing a rule to add certain PFAS to the list of toxic chemicals subject to reporting under EPCRA section 313 and section 6607 of the PPA (more commonly known as the Toxics Release Inventory (TRI)). EPA is also considering establishing reporting thresholds for PFAS that are lower than the usual statutory thresholds (25,000 pounds for manufacturing or processing and 10,000 pounds for otherwise using listed chemicals) due to concerns for their environmental persistence and bioaccumulation potential.

C. What is the Agency's authority for this potential action?

This action is issued under EPCRA sections 313(d) and 328, 42 U.S.C. 11023 *et seq.*, and PPA section 6607, 42 U.S.C. 13106. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986.

Section 313 of EPCRA, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually to EPA and the States. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA, 42 U.S.C. 13106. Congress established an initial list of toxic chemicals that was comprised of 308 individually listed chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that EPA may add a chemical to the list if any of the listing criteria in EPCRA section 313(d)(2) are met. Therefore, to add a chemical, EPA must demonstrate that at least one criterion has been met, but need not determine whether any other criterion has been met. Conversely, to remove a chemical from the list, EPCRA section 313(d)(3) dictates that EPA must demonstrate that none of the criteria in ECPRA section 313(d)(2) have been met. The listing criteria in EPCRA section 313(d)(2)(A) through (C) are as follows:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
- The chemical is known to cause or can reasonably be anticipated to cause in humans: Cancer or teratogenic effects, or serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects.
- The chemical is known to cause or can be reasonably anticipated to cause, because of its toxicity, its toxicity and persistence in the environment, or its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

EPA often refers to the EPCRA section 313(d)(2)(A) criterion as the "acute human health effects criterion;" the EPCRA section 313(d)(2)(B) criterion as the "chronic human health effects criterion;" and the EPCRA section 313(d)(2)(C) criterion as the "environmental effects criterion."

In a final rule that added 286 chemicals and chemical categories to the TRI list, EPA published in the **Federal Register** of November 30, 1994 (59 FR 61432) (FRL–4922–2), a statement clarifying its interpretation of the EPCRA section 313(d)(2) criteria for modifying the EPCRA section 313 list of toxic chemicals. EPA's interpretation of the EPCRA section 313 listing criteria addressed a number of issues including EPA's authority to add chemical categories and EPA's policy on the use of exposure for chemicals that are toxic only at high doses/concentrations.

II. Background Information

A. What is TRI?

EPCRA section 313, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to Pollution Prevention Act section 6607, 42 U.S.C. 13106. Note that TRI does not cover all chemicals, facilities, or types of pollution.

TRI provides information about releases of toxic chemicals from covered facilities throughout the United States; however, TRI data do not reveal whether or to what degree the public is exposed to listed chemicals. TRI data can, in conjunction with other information, be used as a starting point in evaluating such exposures and the risks posed by such exposures. The determination of potential risk to human health and/or the environment depends upon many factors, including the toxicity of the chemical, the fate of the chemical in the environment, and the amount and duration of human or other exposure to the chemical.

For more information on TRI, visit the TRI website at *www.epa.gov/tri.* Additionally, via this website, EPA provides a *Factors to Consider When Using TRI Data document,* which helps explain some of the uses, as well as limitations, of data collected by TRI.

B. What are PFAS?

PFAS are synthetic organic compounds that do not occur naturally in the environment. PFAS contain an alkyl carbon chain on which the hydrogen atoms have been partially or completely replaced by fluorine atoms. The strong carbon-fluorine bonds of PFAS make them resistant to degradation and thus highly persistent in the environment (Refs. 1 and 2). Some of these chemicals have been used for decades in a wide variety of consumer and industrial products (Ref. 1). Some PFAS have been detected at high levels in wildlife indicating that at least some PFAS have the ability to bioaccumulate (Ref. 2). Some PFAS can accumulate in humans and remain in the human body for long periods of time (*e.g.*, months to years) (Refs. 1, 2, and 3). As noted in EPA's Action Plan (Ref. 1), because of the widespread use of PFAS in commerce and their tendency to persist in the environment, most people in the United States have been exposed to PFAS. As a result, several PFAS have been detected in human blood serum (Refs. 1, 2 and 4).

C. Why is EPA considering adding PFAS to the TRI?

Some PFAS may be toxic, persistent in the environment, and accumulate in wildlife and humans. Therefore, releases of some PFAS to the environment and potential human exposure may be of concern. One source of potential exposure to PFAS are releases from industrial facilities that manufacture, process, or otherwise use PFAS. Information on the releases and waste management quantities from such facilities could help EPA and the public identify some potential sources of exposure to PFAS. The TRI is a tool that EPA can use to collect such information. As noted in the EPA Action Plan:

"Currently, no PFAS chemicals are included on the list of chemicals required to report to TRI; however, the EPA is considering whether to add

PFAS chemicals. In considering listing, the EPA must determine whether data and information are available to fulfill the listing criteria and the extent and utility of the data that would be gathered. For example, hazard data required for TRI listing may be readily available for certain PFAS chemicals, but not others. In addition, in considering if TRI will provide useful information to stakeholders, the EPA also will consider if those PFAS are still active in commerce. The process for listing includes notice and comment rulemaking to list PFAS chemicals for reporting prior to adding these chemicals to the TRI for annual reporting." (Ref. 1)

As the first step in the process of adding certain PFAS to the TRI, EPA is issuing this ANPRM to allow all stakeholders the opportunity to comment on the various aspects of adding certain PFAS to the TRI toxic chemical list. Note that adding certain PFAS to the TRI could help inform discussions related to risks to human health and the environment but the information collected through TRI, as previously indicated, would not capture all sources of PFAS releases.

III. What TRI listing actions are being considered?

Currently, approximately 600 PFAS are manufactured (including imported) and/or used in the United States (Ref. 5). The two PFAS that have been studied the most are perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Due to a voluntary phaseout under the 2010/2015 PFOA Stewardship Program, PFOA and PFOS are no longer produced domestically by the companies participating in the Program. However, PFOA and PFOS may still be produced domestically, imported, and used by companies not participating in the PFOA Stewardship Program (Ref. 6). PFOA and PFOS may also be present in imported articles. PFAS such as hexafluoropropylene oxide (HFPO) dimer acid (Chemical Abstract Service Registry Number (CASRN) 13252–13–6) and its ammonium salt (CASRN 62037–80–3), both commonly referred to as GenX, and perfluorobutane sulfonic acid (PFBS) (CASRN 375–73–5) and its salt potassium perfluorobutane sulfonate (CASRN 29420–49–3)), are some examples of short-chain PFAS that have been developed to replace long-chain PFOA and PFOS, respectively. Compared to PFOA and PFOS, most replacement PFAS tend to have less information available about their potential toxicity to human and ecological populations. Through this ANPRM process, EPA is seeking information to determine which PFAS currently active in commerce have sufficient toxicity information available to meet the EPCRA section 313(d)(2) listing criteria. EPA is considering whether to add any PFAS currently active in commerce for which hazard assessments show that they meet the EPCRA section 313(d)(2) listing criteria. Note that one factor EPA considers when determining whether to add a chemical to the TRI list is whether reporting would occur on the chemical if it were to be added.

In addition, for any PFAS that meet the listing criteria, EPA is considering adding these compounds to the list of chemicals of special concern (§ 372.28) and establishing lower reporting thresholds. In the past EPA has lowered the reporting thresholds for persistent, bioaccumulative, and toxic (PBT) chemicals (October 29, 1999, 64 FR 58666 (FRL–6389–11)). For PBT chemicals, with one exception, EPA established two reporting thresholds, 100 pounds for PBT chemicals and 10 pounds for highly PBT chemicals (*i.e.*, those PBT chemicals with very high persistence and bioaccumulation values). Certain PFAS may have persistence and bioaccumulation properties similar to other PBT chemicals where even small amounts of release present a concern. To appropriately capture release information of PFAS, EPA is considering establishing reporting thresholds lower than the statutory thresholds of 25,000 pounds for manufacturing or processing and 10,000 pounds for otherwise using listed chemicals.

PFAS, that meet the ECPRA section 313 listing criteria, could be listed as individual chemicals or as members of PFAS chemical categories. For example, EPA's "Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)" (Ref. 7) states that PFOS (CASRN 1763–23–1) is commonly produced as a potassium salt (CASRN 2795–39–3) and that, while the CASRN given is for linear PFOS, the toxicity studies are commonly based on a mixture of linear and branched PFOS. Therefore, the reference dose (RfD) derived in the 2016 Health Effects Support Document applies to the total linear and branched PFOS. For PFOS it would seem appropriate to create a TRI chemical category that includes all linear and branched isomers of PFOS and any salts of PFOS. PFOA has similar considerations, as may other PFAS that may warrant reporting as a category rather than as individually listed chemicals. EPA may also consider establishing a single chemical category for all PFAS, however, a single category would be of limited use since it would not provide any information about which PFAS are being released and/or managed as waste.

IV. What are the hazard concerns for PFAS?

Some PFAS are known to persist in the environment because they are resistant to degradation and have been shown to bioaccumulate in wildlife and humans (Refs. 1 and 2). There are also concerns that some PFAS may cause adverse human health effects, including reproductive, developmental, cancer, liver, immune, thyroid, and other effects (Refs. 1, 2, 8, and 9).

Based on their physicochemical properties and measured environmental concentrations, some PFAS are considered to be environmentally persistent chemicals (Refs. 1 and 2). In general, most PFAS are resistant to environmental degradation due to their strong carbon-fluorine bonds (Refs. 1 and 2). While PFAS chain length and chemical structure can have implications for environmental fate, PFAS are typically resistant to biodegradation, photooxidation, direct photolysis, and hydrolysis which is consistent with their persistence in soil and water (Ref. 2). Some PFAS, can also degrade or be metabolized to other PFAS such as PFOA or PFOS (Ref. 2). PFAS have been detected in air, surface water, groundwater, drinking water, soil, and food (Ref. 2). The presence of PFAS in many parts of the world, including the Arctic, indicate that long-range transport is possible (Ref. 2).

Under the TRI, bioaccumulation, to the extent it happens, is part of the hazard concerns and will be considered both in the listing criteria and in considering lower reporting thresholds. Bioconcentration factors (BCFs) estimated from an octanol-water partition coefficient (K_{ow}) or measured in aquatic tests, have typically been used to assess bioaccumulation potential. K_{ow} and the associated BCFs are based on the partitioning of organic chemicals into octanol or lipids. However, for PFAS such as PFOA and PFOS partitioning appears to be more related to their protein binding properties than to their lipophilicity (Refs. 8 and 9). Since K_{ow} does not provide a reliable estimate of bioaccumulation potential for these chemicals, field evidence of bioaccumulation is preferable. Field measured bioaccumulation factors (BAFs), and biomagnification factors (BMFs) or trophic magnification factors (TMFs) are considered more appropriate

indicators of the potential for PFAS, such as PFOA and PFOS, to accumulate in fish, other wildlife, and humans (Refs. 8, 9, 10, and 11). The trophic magnification data for PFOA and PFOS was deemed sufficient to consider them to be bioaccumulative by the Stockholm Convention Persistent Organic Pollutants Review Committee in 2015 (Ref. 12).

While the toxicity of PFOA and PFOS has been studied extensively, there is less data available for other PFAS (Ref. 2). Differences in PFAS chain length and chemical structure can have implications for environmental fate, bioaccumulation, metabolism, and toxicity (Ref. 1). As part of EPA's PFAS Action Plan, the Agency is continuing to collect, systematically review, and evaluate available toxicity data for other PFAS that may help determine whether exposure to structurally similar PFAS results in similar toxic effects (Ref. 1).

V. What EPA hazard assessments and other toxicity data are available for PFAS?

To date EPA has published two assessments of PFAS: (1) Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) and (2) Health Effects Support Document for Perfluorooctanoic Acid (PFOA) (Refs. 7 and 13). These two documents could be used to determine whether PFOA, PFOS, and related chemicals (*e.g.*, their salts) meet the EPCRA section 313(d)(2) listing criteria. EPA has also developed two new draft PFAS assessments for public comment: (1) Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252–13–6 and CASRN 62037–80–3) Also Known as "GenX Chemicals" and (2) Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375–73–5) and Related Compound Potassium Perfluorobutane Sulfonate (PFBS) (CASRN 29420–49–3) (Refs. 14 and 15). Once these documents are finalized, EPA expects these assessments will provide a basis for determining whether GenX chemicals and PFBS meet the EPCRA section 313(d)(2) listing criteria.

In addition, EPA is working on hazard assessments for the following PFAS containing varying degrees of available toxicity information relevant for human health assessment purposes: Perfluorononanoic acid (PFNA), perfluorobutanoic acid (PFBA), perfluorodecanoic acid (PFDA), perfluorohexanoic acid (PFHxA), and perfluorohexane sulfonic acid (PFHxS) (Ref. 16). Once finalized, EPA expects these assessments will provide a basis for determining whether these chemicals meet the EPCRA section 313(d)(2) listing criteria.

EPA has also collected scientific literature on approximately 30 PFAS. This list of PFAS and the available scientific literature is posted at *https://hero.epa.gov/hero/index.cfm/litbrowser/public/#PFAS*. For some of these PFAS, there may be epidemiological and/or experimental animal toxicity data available for review and evaluation of suitability to inform potential human health effects.

Lastly, EPA is collaborating with the National Toxicology Program (NTP) to study individual PFAS and PFAS as a chemical class. Specifically, the NTP has conducted toxicology studies to evaluate and identify the adverse effects of certain PFAS chemicals including PFBS, PFHxS, PFOS, PFHxA, PFOA, PFNA, and PFDA (*https://www.niehs.nih.gov/health/topics/agents/pfc/index.cfm*). NTP continues to assess the potential health effects of PFAS through a large multi-faceted research effort (*https://ntp.niehs.nih.gov/results/areas/pfas/index.html*).

The Agency relies on EPA hazard assessments and externally peer-reviewed hazard assessments from other federal agencies in making determinations as to whether a chemical meets the EPCRA section 313 listing criteria. EPA will consider all PFAS assessments on the human health and environmental effects of PFAS that are available from all sources, including those being conducted by other federal agencies.

VI. What information is EPA requesting?

EPA is seeking comments on which of the approximately 600 PFAS currently active in U.S. commerce the Agency should consider evaluating for potential addition to the EPCRA section 313 list of toxic chemicals. EPA would also like to receive comments on whether there are data available to inform how to list PFAS, *i.e.*, as individual chemical listings, as a single category, as multiple categories or as a combination of individual listings and category listings. Note that when chemicals are listed as a category, the TRI reports submitted would include combined data for all members of the category, such that there are no data reported specific to any individual member of the category.

EPA is also seeking comments on the appropriate reporting thresholds for PFAS. Reporting thresholds should be set at an appropriate level to capture most of the releases of PFAS from the facilities that submit reports under EPCRA section 313. Finally, EPA would like to receive any additional information on human health and environmental toxicity, persistence, and bioaccumulation of PFAS that would help determine if they meet the EPCRA section 313 listing criteria.

VII. What are the next steps EPA will take?

EPA intends to carefully review all the comments and information received in response to this ANPRM, as well as previously collected and assembled studies. Once that review is completed, EPA may supplement the collected information with additional hazard assessments to determine whether some PFAS meet the EPCRA section 313(d)(2) criteria. Should EPA decide to move forward with this action, the next step will be to publish a proposed rule to add certain PFAS to the EPCRA section 313 toxic chemical list and set the appropriate reporting thresholds. At that time, the public will have the opportunity to comment on EPA's proposal.

VIII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA. EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan. EPA 823R18004. U.S. Environmental Protection Agency, Washington, DC. February 2019. Available from: *https://www.epa.gov/pfas/epas-pfas-action-plan*.
2. ATSDR. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Perfluoroalkyls—Draft for Public Comment. June 2018. Available from: *https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf*.
3. USEPA. Basic Information on PFAS. U.S. Environmental Protection Agency, Washington, DC. Available from: *https://www.epa.gov/pfas/basic-information-pfas*.
4. Department of Health and Human Services, Centers for Disease Control and Prevention. Fourth National Report on Human Exposure to Environmental Chemicals. Pages 247–257, 2009. Available from: *https://www.cdc.gov/exposurereport/pdf/fourthreport.pdf*.
5. USEPA. Toxic Substances Control Act (TSCA) Chemical Substance Inventory. U.S. Environmental Protection Agency, Washington, DC. Available from: *https://www.epa.gov/tsca-inventory*.