

PRE-PUBLICATION NOTICE

On October 1, 2024, Michal Freedhoff, the EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, signed the following document:

Action: **Proposed Rule**
Title: **Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory (TRI)**
FRL #: **9313-01-OCSP**
Docket ID #: **EPA-HQ-OPPT-2023-0538**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA-HQ-OPPT-2023-0538; FRL-9313-01-OCSPP]

RIN 2070-AL03

Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory (TRI)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to add 16 individually listed per- and polyfluoroalkyl substances (PFAS) and 15 PFAS categories to the Toxics Release Inventory (TRI) list of toxic chemicals subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA) to comply with the National Defense Authorization Act for Fiscal Year 2020 (NDAA). EPA also addresses how PFAS categories should be treated. Separately, EPA discusses what events may trigger the automatic addition of a PFAS to the TRI pursuant to the NDAA. This discussion does not propose to list chemicals to TRI pursuant to the NDAA, but rather describes what EPA documents and activities involving PFAS would trigger an automatic addition under the NDAA.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments on the information collection provisions submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) are best assured of consideration by OMB if OMB receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0538, through <https://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. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Rachel Dean, Data Gathering, Analysis, Management, and Policy Division, Mailcode 7406M, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1303; email address: dean.rachel@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or otherwise use any of the PFAS listed in this rule. The following list of North American Industry 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*, 212323*, 212390*, 488390*, 5131*, 512230*, 512250*, 516210*, 519290*, 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): 212114, 212115, or 212220, 212230, 212290*; or 2211*, 221210*, 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, 424710 (corresponds to SIC code 5171, Petroleum Bulk Terminals and Plants); 425120 (limited to facilities previously classified in SIC code 5169, Chemicals and Allied Products, Not Elsewhere Classified); 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.

- Facilities that the EPA Administrator has specifically required to report to TRI pursuant to a determination under EPCRA section 313(b)(2).

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 is affected by this action, you should carefully examine the applicability criteria in 40 CFR part 372, Subpart B. Federal facilities are required to report under Section 6(a) and (b) of Executive Order 14096 (88 FR 25251, April 21, 2023), titled “Revitalizing Our Nation’s Commitment to Environmental Justice for All.” 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 the Agency taking?*

EPA is proposing to add 16 individually listed per- and polyfluoroalkyl substances (PFAS) and 15 PFAS categories to the TRI 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). The proposed PFAS chemical categories are comprised of an acid, associated salts, associated acyl/sulfonyl halides, and an anhydride. EPA is proposing to set a manufacturing, processing, and otherwise use reporting threshold of 100 pounds for each individually listed PFAS and PFAS category being proposed for listing by this rulemaking and to designate all PFAS listed under this action as chemicals of special concern. EPA also proposes to reclassify some individually-listed PFAS previously added to the TRI by sections 7321(b) and (c) of the National Defense Authorization Act for Fiscal Year 2020 (NDAA) as part of the proposed PFAS chemical categories. Doing so would align such listings with the approach provided for the candidate additions proposed in this rulemaking. This would change these chemicals from being individually listed to being part of the applicable chemical category. Finally, EPA also addresses what events may trigger the automatic addition of PFAS to the TRI list pursuant to the framework established by the NDAA section 7321(c).

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

EPA is taking this action pursuant to EPCRA sections 313(d) and 328 (42 U.S.C. 11023(d) and 11048), and section 7321(d) of the FY2020 NDAA (Pub. L. 116-92, section 7321). EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986. EPCRA section 313 is also referred to as the Toxics Release Inventory (TRI).

1. EPCRA authorities.

EPCRA section 313 requires owners/operators of certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their facilities' environmental releases and other waste management information on such

chemicals annually. These facility owners/operators must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA (42 U.S.C. 13106).

Under EPCRA section 313(c), Congress established an initial list of toxic chemicals subject to EPCRA toxic chemical reporting requirements 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 determine that at least one criterion is met, but need not determine whether any other criterion is met. Conversely, to remove a chemical from the list, EPCRA section 313(d)(3) dictates that EPA must determine that none of the criteria in EPCRA section 313(d)(2) are 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.” EPA published a statement in the *Federal Register* of November 30, 1994 (59 FR 61432) (FRL-4922-2)) clarifying its interpretation of the EPCRA section 313(d)(2) and (d)(3) criteria for modifying the EPCRA section 313 list of toxic chemicals.

2. FY 2020 NDAA authorities.

The FY 2020 NDAA provides several avenues for PFAS to be added to the TRI. Section 7321(b) of the FY 2020 NDAA, entitled “Immediate Inclusion,” provides that specific PFAS shall be deemed included in the TRI beginning January 1 of the calendar year following the date of enactment of the NDAA. Section 7321(c) of the FY 2020 NDAA, titled “Inclusion following Assessment,” provides that PFAS shall be added to the TRI beginning January 1 of the year after the date on which certain events occur including the date on which the Administrator finalizes a toxicity value for a PFAS. These events include the following: EPA finalizing a toxicity value for a PFAS; including a PFAS in a Significant New Use Rule (SNUR) issued under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) or addition to an existing SNUR; and designating a PFAS as active on the TSCA Chemical Substance Inventory (TSCA Inventory). Section 7321(d) of the FY 2020 NDAA, in turn, requires EPA to determine within two years of the date of enactment of the FY 2020 NDAA whether certain PFAS (including classes) meet any of the listing criteria of EPCRA section 313(d)(2). As stated in Section 7321(d)(2) of the FY 2020 NDAA, the PFAS for which EPA must make such determinations include 15 PFAS described by name, each PFAS or class of PFAS for which a method to measure levels in drinking water has been validated by the Administrator, and each PFAS or class of PFAS that is used to manufacture fluorinated polymers, as determined by the Administrator. Section 7321(d)(3) of the FY 2020 NDAA requires that those PFAS that EPA determines meet the EPCRA section 313(d)(2) listing criteria be added to the EPCRA section 313 toxic chemical list

within two years of such determination.

D. What are the estimated incremental impacts of this action?

EPA prepared an economic analysis for this action titled, “Economic Analysis for the Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting; Proposed Rule (RIN 2070-AL03)” (Ref. 1), which presents an analysis of the costs of the proposed addition of 16 individually listed PFAS and 15 categories of PFAS identified in this document to the TRI list of chemicals. This economic analysis is available in the docket and is summarized here.

EPA estimates that this action would result in an additional 356 to 1,110 TRI reporting forms (*i.e.*, Form Rs) being filed annually. EPA estimates that the costs of this action will be approximately between \$2,114,886 and \$6,594,234 in the first year of reporting and approximately \$1,007,093 and \$3,140,123 in the subsequent years. In addition, EPA has determined that, of the 277 to 865 small businesses affected by this action, none are estimated to incur annualized cost impacts of more than 1% of revenues. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities as further discussed in Unit X.C.

E. What should I consider as I prepare my comments for EPA?

1. Submitting CBI.

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will

not be disclosed except in accordance with procedures set forth in 40 CFR part 2 and/or 40 CFR part 703, as applicable.

2. Tips for preparing your comments.

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background

A. What are “PFAS”?

PFAS are synthetic organic compounds that do not occur naturally in the environment. PFAS typically contain a linear or branched alkyl carbon chain on which the hydrogen atoms have been partially (*i.e.*, polyfluorinated) or completely (*i.e.*, perfluorinated) replaced by fluorine atoms. In general, the strong carbon-fluorine bonds of PFAS make them resistant to degradation and thus highly persistent in the environment (Ref. 2, 3, 4); though, some PFAS (*e.g.*, certain perfluorobutanesulfonyl fluoride and perfluorobutanesulfonic anhydride in the case of perfluorobutanesulfonic acid (PFBS)), are known to become more toxic as they degrade in the environment. Some of these chemicals have been used for decades in a wide variety of consumer and industrial products (Ref. 2, 3, 4). Some PFAS have been detected in humans and wildlife indicating that at least some PFAS have the ability to bioaccumulate (Ref. 2, 4). 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 (Ref. 3, 5, 6). PFAS can accumulate in humans and remain in the human body for long periods of time (*e.g.*, months to years) (Ref. 3, 4); several PFAS have been detected in human blood serum (Ref. 3, 4, 5, 6).

Section 7321 of the NDAA does not define “PFAS.” Elsewhere in the NDAA, PFAS are defined for purposes specific to the applicable section. For example, in section 332, PFAS are defined as “man-made chemicals with at least one fully fluorinated carbon atom.” Beyond the

NDAA, various scientific bodies and regulatory agencies—such as the European Chemical Agency (ECHA) and the Swedish Chemicals Agency—are aligned with the Organization of Economic Co-operation and Development (OECD) (Ref. 7, 8) in defining PFAS using broad, inclusive definitions.

Because the FY2020 NDAA does not provide a complete list of the PFAS that EPA must consider for inclusion in the TRI, EPA used a structural definition of PFAS being used for other chemical regulatory activities at EPA (*e.g.*, TSCA section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances final rule (hereafter, the “TSCA PFAS Data Reporting Rule”) (88 FR 70516) (Ref. 2) for the purpose of scoping chemicals for this proposed rule. Thus, for purposes of identifying candidates for this proposed TRI listing of PFAS, PFAS is defined to include chemicals that contain at least one of these three structural moieties:

$R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated;

$R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; or

$CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons.

EPA notes that this definition may not be identical to other definitions of PFAS used within EPA and/or by other organizations. The term “PFAS” has been used broadly by many organizations for their individual research and/or regulatory needs. As an example, the definition that EPA applied for this proposal is a more precise characterization than the very broad and inclusive definitions provided in other sections of the NDAA (described above). Various programs or organizations have distinct needs or purposes apart from EPA’s Office of Chemical Safety and Pollution Prevention (OCSPP). Therefore, different definitions of the term “PFAS” may be appropriate for other purposes – some are meant to describe the broader universe of PFAS as a whole and others are intended to be regulatorily- and context-specific. The Agency

notes that this perspective, that different users may have different decision contexts or needs and no single PFAS characterization or definition meets all needs, is shared by many other organizations, including OECD (see page 29, (Ref. 7)).

EPA recognizes that there were various options for applying a definition of “PFAS” for scoping purposes and acknowledges that there may be other rules or programs that apply different definitions to meet their own needs. Notably, use of the definition described in this unit aligns this proposal with other regulatory actions by OCSPP, such as the TSCA PFAS Data Reporting Rule (Ref. 2), thereby providing a consistent understanding across TSCA and TRI for purposes of assessing hazard information. Further, aligning the TRI definition with the definition being used for various TSCA activities helps ensure that this TRI rulemaking focuses on chemicals most likely to be active in commerce and thus are more likely to be manufactured, processed, and/or otherwise used by facilities in quantities that may trigger TRI reporting requirements. As indicated previously, the TSCA PFAS Data Reporting Rule provides additional discussion of this definition and the explanation for its use for certain regulatory actions (Ref. 2).

B. How did EPA identify PFAS for purposes of identifying PFAS to be added under 7321(d) of the NDAA?

The first step EPA took in identifying PFAS as required by section 7321(d) of the NDAA was to create a list of all potential chemical candidates to consider. Section 7321(d)(2)(A) through (O) provides a list of PFAS for which the Administrator must determine whether any of the EPCRA 313(d)(2) criteria are met. Paragraphs (A) through (M) of section 7321(d)(2) identify specific PFAS by name and/or an identifier (typically Chemical Abstracts Service Registry Number (CASRN)). Paragraph (N) identifies any PFAS for which a method to measure levels in drinking water has been validated by the Administrator. At the time of the NDAA’s enactment, EPA had approved two methods to analyze drinking water samples to ensure compliance with

regulations that include PFAS, Method 533 and 537.1. Together, Method 533 and Method 537.1 identify 29 PFAS, of which 23 are distinct from the PFAS identified in paragraphs (A) through (M).

Paragraph (O) generally indicates that EPA must consider for listing any PFAS used to manufacture fluorinated polymers, as determined by the Administrator. A polymer is a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units. A monomer is a chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules. A monomer reacting with other monomer molecules forms a larger polymer chain or network in a process called polymerization. Accordingly, a fluorinated polymer is a polymer that includes fluorine.

To determine which PFAS qualify as PFAS used to manufacture fluorinated polymers pursuant to paragraph (O), EPA relied on the CompTox Chemicals Dashboard (CompTox) (an EPA web-based application that provides public access to data on more than 1.2 million chemicals) (comptox.epa.gov/dashboard) (Ref. 9). CompTox includes a broad list of PFAS chemicals (see the Dashboard chemical list "EPA PFAS chemicals without explicit structures," available at <https://comptox.epa.gov/dashboard/chemical-lists/PFASDEVI>) (Ref. 10), which includes fluorinated polymers. EPA downloaded this list and then, to identify polymers, filtered out likely non-polymers by first removing any chemicals listed as "compounds with," "reaction products," or "poly(difluoromethane)-R". Such substances would not be characterized as "fluorinated polymers." The remaining chemicals were identified as potential fluorinated polymers as per the language provided by paragraph (O).

Then, of the remaining potential fluorinated polymers, EPA determined whether a PFAS was used to manufacture the polymer. EPA reviewed the preferred name or other associated synonym that provided descriptive information of the molecular structure of the polymer or

information about the chemicals used to create the respective polymer. These descriptive synonyms were used to identify fluorinated substructures of the polymer and/or each fluorinated substance used to make the polymer (*i.e.*, EPA identified each component of a polymer that is a fluorinated chemical based on its name). For example, for the polymer in CompTox labeled “POLYFLGSID_897590” (CASRN 68586-13-0), its constituent monomers were not apparent from that name. However, its synonym as registered within CompTox was “2-Propenoic acid, 2-[[heptadecafluorooctyl)sulfonyl]methylamino]ethyl ester, polymer with 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate, α -(2-methyl-1-oxo-2-propenyl)- ω -hydroxypoly(oxy-1,2-ethanediyl), α -(2-methyl-1-oxo-2-propenyl)- ω -[(2-methyl-1-oxo-2-propenyl)oxy]poly(oxy-1,2-ethanediyl), 2-[methyl[(pentadecafluoroheptyl)sulfonyl]amino]ethyl 2-propenoate, 2-[methyl[(tridecafluorohexyl)sulfonyl]amino]ethyl 2-propenoate and 2-[methyl[(undecafluoropentyl)sulfonyl]amino]ethyl 2-propenoate,” which allowed EPA to identify five constituent monomers and determine whether any met the definition of PFAS used for purposes of scoping for this rule. EPA then identified as many unique CASRNs for these individual monomers as possible and compared them to the PFAS already on the TRI list as well as those already under review or subject to review via another requirement of the NDAA (*e.g.*, any PFAS for which a method to measure levels in drinking water has been validated by the Administrator that are already on the TRI list, NDAA section 7231(d)(2)(N)). Additionally, EPA removed any chemicals identified via this process that did not meet the TSCA PFAS Data Reporting Rule’s structural definition of PFAS (Ref. 2) (see Unit II.A.).

NDAA section 7321(d)(2) uses the term “including” as a preface to the PFAS described by paragraphs (A) through (O). EPA thus interprets paragraphs (A) through (O) as examples of the larger universe of PFAS this section requires EPA to consider. Accordingly, EPA also considered additional PFAS beyond those described by paragraphs (A) through (O). To assist in

identifying such chemicals, EPA applied the definition of PFAS (see Unit II.A.) and looked for chemicals that fit that definition. Additionally, EPA considered its previously articulated position on the use of manufacturing volume thresholds (*e.g.*, 58 FR 63500, December 1, 1993) (FRL-4904-6)) and, as in past chemical reviews (*e.g.*, 59 FR 61432, November 30, 1994) (FRL-4922-2) (Ref. 11), applied a screening process to screen out PFAS for which no reports would be expected to be submitted in order to focus its listing actions on chemicals for which TRI reporting is anticipated. TRI previously used Chemical Data Reporting (CDR) data to help identify chemicals for which TRI reporting would be unlikely due to no reports having been submitted to CDR for any such chemicals. However, because the CDR reporting threshold (either 25,000 pounds or 2,500 pounds, depending on whether certain TSCA actions apply to the given chemical substance) is above the 100-pound threshold being proposed here, EPA determined it more appropriate to consider a broader universe of chemicals than just those identifiable using the CDR production volume screen.

To assist EPA in identifying PFAS for which TRI reporting could be anticipated, the Agency considered PFAS categorized as reportable pursuant to the TSCA PFAS Data Reporting Rule (Ref. 2), given that rule's focus on manufactured PFAS. (For more discussion on the proposed reporting threshold for this action, see Unit V.). PFAS reportable pursuant to the TSCA PFAS Data Reporting Rule are primarily characterized as "active" in commerce pursuant to the TSCA Inventory, though the TSCA PFAS Data Reporting Rule, includes chemical substances beyond those on the TSCA Inventory (*e.g.*, PFAS with a low-volume exemption). TRI reporting on such chemicals could occur since they may be manufactured, processed, and/or otherwise used. Thus, it is appropriate to include such chemicals for consideration for purposes of this rule. Additionally, EPA considered chemicals that might not be subject to the TSCA PFAS Data Reporting Rule, but which might nevertheless be possible listing candidates for TRI (*e.g.*, PFAS

regulated pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act).

EPA did not screen out (*i.e.*, remove as a candidate) any PFAS listed in NDAA section 7321(d)(2)(A) through (O) based on TSCA Inventory status. EPA did, however, remove any chemicals with CBI claims related to their identity to focus on chemicals for which the Agency could publicly provide hazard data to support listing. EPCRA section 313(d)(2) requires EPA to support proposed listings with “sufficient evidence.” Consequently, it could be difficult for the public to review and comment on such evidence where the public is not aware of the identity of the chemical. Further, it would take additional Agency resources to ensure that such information is provided in a manner that protects the privileged information pursuant to the applicable CBI claim. However, current CBI claims concerning identity of a given PFAS are being reviewed by EPA. Further, additional reviews will be triggered by forthcoming CDR filings as well as reporting being required pursuant to the TSCA section 8(a)(7) PFAS Data Reporting Rule. EPA will consider PFAS whose identities are disclosed due to this review process as candidates for potential future additions.

For chemicals other than the NDAA section 7321(d)(2)(A) through (O) candidates and except for purposes of identifying salts associated with acids being proposed for listing, EPA generally removed from consideration PFAS which were not active on the TSCA Inventory. The Agency also removed chemicals with CBI claims related to their identity, when locating hazard information. By excluding chemicals with CBI claims related to their identity for purposes of identifying hazard information, EPA focused on publicly available literature with which to support the TRI listing process. Please see Unit IV. for details on CBI claims related to potential category chemicals.

Though EPA generally used the TSCA Inventory as a means to screen out chemicals, aside from the specifically mentioned chemicals in the NDAA, the Agency also considered

certain chemicals that are not on the TSCA Inventory (those that are regulated under statutes other than TSCA due to their uses). For example, TSCA does not regulate uses of a chemical as a pesticide or drug. EPCRA does not limit the scope of reportable chemical substances by use of the chemical. Thus, EPA determined it appropriate not to apply the TSCA Inventory screening process where EPA is aware of the manufacture of a chemical even though it is not on the TSCA Inventory. For such chemicals, the Agency considered available toxicity data to determine if there is sufficient evidence to support a TRI listing. Accordingly, EPA is including certain pesticides registered with the EPA (*i.e.*, broflanilide, hexaflumuron, pyrifluquinazon, and tetraconazole) as well as certain pharmaceutical chemicals for which the Agency anticipates TRI reporting would occur were the Agency to list such chemicals. Relatedly, EPA is also proposing to clarify that pesticide registrations that establish final toxicity values for PFAS constitute finalization of a toxicity value by the Administrator that result in the automatic addition of the PFAS to the TRI (see Unit VII.). This approach captured a large universe of PFAS for which EPA screened for literature that could support a TRI listing pursuant to the ECPRA section 313(d)(2) criteria. For PFAS for which such literature was located, the Agency produced either TRI listing support documents, as provided in the docket, or relied on assessments that had been or are being produced for reasons separate from this rulemaking.

Additionally, EPA explored additional means for identifying PFAS, as well as other chemicals, as candidates for TRI listing, and the Agency is soliciting comment on this approach as well as other approaches that it might take to expand its process for identifying and proposing chemicals for addition to the TRI list. To this end, the TRI Program queried the ECOTOX Knowledgebase (ECOTOX) (Ref. 12) and the EPA Health Assessment Workspace Collaborative (EPA HAWC) project for the Systematic Evidence Map for Over One Hundred and Fifty Per- and Polyfluoroalkyl Substances (PFAS) publication (PFAS 150 (2022) project for shorthand)

(Ref. 13, 14).

ECOTOX is a web-based application for locating single chemical toxicity data for aquatic life, terrestrial plants, and wildlife. EPA created and maintains ECOTOX to address the need for assembled environmental toxicity data as the number of chemicals introduced into commerce continues to grow and regulatory mandates require safety assessments for a greater number of chemicals. ECOTOX is currently the world's largest compilation of curated ecotoxicity data, providing support for assessments of chemical safety and ecological research through systematic and transparent literature review procedures. ECOTOX utilizes well-established standard operating procedures with a strict screening pipeline and process to only include applicable data from several well-recognized databases (*e.g.* Scopus, ProQuest, PubAg, Web of Science). Comprehensive chemical-based literature searches are conducted by experts in the field and the resulting citations are screened at title/abstract level followed by manual full-text review. If a study passes pipeline screening at the title/abstract level, the full text is then manually reviewed to determine applicability for inclusion to ECOTOX and can be excluded for a number of reasons (Ref. 15). Inclusion criteria include: exposure to a single chemical (test substance) that can be unequivocally identified, test organism unequivocally identified and relevant for ecological assessments, reported exposure concentration(s) and duration, and inclusion of control(s). Exclusion reasons are, for example: lack of an appropriate description of study methods to determine test substance, test organism, exposure duration/concentration; species relevant for human health hazard (rather than ecological hazard); or observational survey study; among other reasons (Ref. 15). Furthermore, many data fields are extracted for each study in ECOTOX that can serve as a metric for evaluation of study design, including: test method; dose; exposure sample number and duration; analytical methods and measurements; and experimental design. In addition to identification of studies through ECOTOX-specific literature

searches, studies that EPA has reviewed with its systematic review process are also added to ECOTOX (*i.e.*, for TSCA Risk Evaluations).

EPA HAWC is a web-based application for developing environmental and human health assessments that promotes transparency, data usability, and understanding of the data and decisions supporting an assessment. EPA HAWC allows the data and decisions supporting an assessment to be evaluated and managed using a collection of features that support methods including literature screening, study evaluation, and data extraction. EPA HAWC serves as a comprehensive landscape of study details and data supporting an assessment, and it serves as a public repository for the study quality decisions and extracted data used to support an assessment and provides rich, interactive visuals of the results both within and across the evidence (<https://www.epa.gov/risk/health-assessment-workspace-collaborative-hawc>). For EPA assessments that have used the EPA HAWC application to aid in support conducting those assessments, which include certain TSCA risk evaluations and IRIS and other ORD assessments, the system contains information on the collective, publicly available studies and data that were used in those assessments (<https://hawc.epa.gov/assessment/public/>).

Both ECOTOX and EPA HAWC are web-based applications that provide study quality evaluation and dose-response analysis, among other information, that can be analyzed as evidence for purposes of TRI chemical listing decisions. EPA HAWC differs from ECOTOX in that ECOTOX is a comprehensive Knowledgebase providing single chemical environmental toxicity data on aquatic and terrestrial species whereas EPA HAWC is an interactive, expert-driven, content management system for human health assessments. The Agency has identified one chemical ((1H,1H, 2H, 2H-perfluorooctane sulfonic acid (6:2 FTS) (CASRN 27619-97-2)) from a project within EPA HAWC, supporting data for the Systematic Evidence Map for Over One Hundred and Fifty Per- and Polyfluoroalkyl Substances (PFAS) (PFAS 150 (2022) project)

(Ref. 14), that it determined would meet the TRI listing criteria. The Agency also identified one chemical (fulvestrant (CASRN 129453-61-8)) from ECOTOX that it determined would meet the TRI listing criteria. Because the content from each of these applications is produced by a consistent, published methodology based on generally accepted scientific principles, the Agency considers these applications to be appropriate tools for establishing sufficient evidence to support TRI listings analysis arising from information provided by these applications. More information is provided in Unit III. on the specific chemicals being proposed for listing, and EPA is, in Unit VIII., soliciting comment on using either or both of these applications, as well as other sources of such data, to support TRI listing decisions.

The Agency is unaware of evidence on PFAS beyond the chemicals identified in this proposal that provide data sufficient for a TRI listing. EPA solicits comment on PFAS that the Agency might have overlooked where existing hazard literature would support a finding required by EPCRA section 313(d)(2) for a TRI chemical listing. In submitting literature for EPA's consideration, please refer to previous TRI chemical listing rule discussions for further guidance on how the Agency evaluates evidence in determining whether a study or data is sufficient for TRI listing, and whether the sufficient data support an EPCRA section 313 listing: see the Addition of 12 Chemicals final rule (87 FR 73475; November 30, 2022 (FRL-5927-02-OCSP)) (Ref. 16) and the 1994 chemical list expansion final rule (59 FR 61432; November 30, 1994 (FRL-4922-2)) (Ref. 11).

The Agency also searched for salts, acyl/sulfonyl halides, and anhydrides associated with PFAS identified for addition (as these are known hydrolysis precursors to the PFAS acid), as well as for PFAS added to TRI pursuant to previous activities (*i.e.*, listed due to NDAA section 7321(b) and (c)). Salts, acyl/sulfonyl halides, and the anhydride associated with a given PFAS acid are expected to have similar or higher toxicity (where the base comprising the salt [counter

ion] presents an additional toxicity concern) to the associated acid. For purposes of describing these categories, EPA is proposing to list identified salts, acyl/sulfonyl halides, and the anhydride associated with each PFAS category. However, listing such chemicals is meant to be an illustrative rather than exhaustive list. Put another way, these proposed PFAS categories would include all of the salts, acyl/sulfonyl halides, and anhydride of the given PFAS acid rather than just those listed as examples (*i.e.*, as proposed, the listing of an acid as a TRI category will automatically include associated salts, acyl/sulfonyl halides, and the anhydride, even if not explicitly mentioned).

Any chemicals that were statutorily added to the TRI list pursuant to NDAA sections 7321(b) or (c), or already on the TRI list prior to the NDAA, are not candidates for this rulemaking due to their already being on the TRI list. However, EPA is proposing to change some such individual listings to category listings described in Unit III.B.

Lastly, for some of the chemicals expressly described by 7321(d)(2)(A) through (N), EPA's literature review did not reveal information sufficient to support a proposed listing. Accordingly, the Agency is not proposing to add such chemicals to the TRI list and as such, is not providing listing support documents to support TRI listings of any such chemicals. As indicated above, EPA is soliciting information related to chemicals in this proposal (for chemicals proposed for listing as well as for chemicals not identified as listing candidates). See Unit IV.A. for a list of these chemicals.

C. What is EPA's general rationale for proposing to list these PFAS pursuant to section 7321 of the NDAA?

Based on EPA's review of the publicly available toxicity data, EPA has concluded that the PFAS proposed for addition to the EPCRA section 313 toxic chemical list can reasonably be anticipated to cause adverse chronic human health effects at moderately low to low exposure

doses and/or environmental effects at low concentrations. EPA concludes the data show that these PFAS have moderately high to high human health toxicity and/or are highly toxic to aquatic organisms. Further, some of the PFAS (*e.g.*, certain perfluorobutanesulfonyl fluoride and perfluorobutanesulfonic anhydride in the case of perfluorobutanesulfonic acid (PFBS)) being proposed for listing are known to become more toxic as they degrade in the environment to other PFAS included in this proposed rule; in other words, some of the PFAS proposed for listing are known to be the source of transformation/degradation products that are highly toxic. Therefore, EPA believes that the evidence is sufficient for listing all PFAS in this proposed rule (as described in Unit III.B. and C.) on the EPCRA section 313 toxic chemicals list pursuant to EPCRA section 313(d)(2)(B) and/or (C).

EPA has generally determined that it is not necessary or appropriate to perform an exposure assessment in order to consider listing TRI chemicals. EPA has considered the carcinogenicity and the potential for other serious or irreversible chronic human health effects as part of evaluating whether to list, but the Agency has not performed an exposure assessment pursuant to EPCRA section 313(d)(2)(B) (see 59 FR 61440–61442). EPCRA section 313 specifically requires that exposure be considered for listing a chemical pursuant to section 313(d)(2)(A). The statute mandates that EPA consider whether “a 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.” However, statute is silent on the issue of exposure considerations for the section 313(d)(2)(B) and (C) criteria. The language of section 313 does not prohibit EPA from considering exposure factors when making a finding under either section 313(d)(2)(B) or section 313(d)(2)(C), though such considerations are not required.

Accordingly, generally EPA does not consider exposure for chronic human health effects

or environmental effects as doing so is not statutorily required pursuant to EPCRA section 313(d)(2)(C) (see 59 FR 61440–61442).

Not only does EPCRA not require EPA to perform an exposure assessment for listings pursuant to section 313(d)(2)(B) or (C), but the intent of EPCRA also warrants forgoing exposure assessments for TRI listings. EPCRA section 313 charges EPA with collecting and disseminating information on releases, among other waste management data, so that communities can estimate local exposure and local risks; risks which can be significantly different than those which would be assessed using generic exposure considerations. The intent of EPCRA section 313 is to ensure that communities in which the releases occur have information needed both to consider the significance of risks and potential ways to address them. Similarly, TRI data helps the federal government, states, tribes, and local governments determine appropriate actions with regard to potential risks. This basic empowerment at national and local levels is a cornerstone of the right-to-know program.

Therefore, in accordance with EPA’s standard policy on the use of exposure assessments (see November 30, 1994 (59 FR 61432, FRL-4922-2) (Ref. 11)), an exposure assessment is neither necessary nor appropriate for determining whether any of the PFAS in this proposed rule meet the criteria of EPCRA section 313(d)(2)(B) or (C).

EPA is also proposing to list certain categories of PFAS to include an acid and associated salts and acyl/sulfonyl halides. EPA’s position is that salts will have at least the same hazard concerns as the associated acid. Categorizing salts with their associated acids will reduce the overall number of individual chemical listings while helping to ensure that TRI reporting is informative as it relates to the hazard for a given acid being proposed for listing. Further, the NDAA directs EPA to determine “whether the substances and classes of substances” described by section 7321(d) meet the TRI-listing criteria, which indicates congressional support for TRI to

establish categories to help facilitate such reporting. Further, whereas ions were previously included on the TRI list pursuant to the NDAA section 7321(c), EPA is proposing to remove any individually-listed CASRNs of ions related to PFAS that are on the TRI list since the proposed PFAS acids are expected to dissociate into ions under normal environmental conditions. This is consistent with EPA's longstanding interpretation that adding an ion is effectively adding a category of related compounds that dissociate into the ion (see 59 FR 61432, 61460; November 30, 1994), regarding the listing of a nitrate compounds category, which encompasses reporting of the nitrate ion released) (Ref. 11)). Therefore, reporting for the PFAS categories in Unit III.B. and C includes PFAS ions because reporting on associated chemicals would be required. Explanations to support each proposed listing are provided in Unit III.

III. Technical Evaluation of the Toxicity of the PFAS Being Proposed for Addition

EPA used a combination of existing Agency human health assessments and listing support documents specifically prepared for this action to evaluate the available data on human health effects and/or environmental effects associated with the PFAS being proposed for listing, as identified by the process described in Unit III.B. to identify sufficient evidence to support chemical listings. Summaries of the available human health effects and environmental effects information that support listing these PFAS under EPCRA section 313 are provided in Unit IV. Where final EPA PFAS assessments are available, a brief summary of the assessment findings is provided.

For PFAS without a final published hazard assessment, more detailed descriptions of the results and analyses supporting the listing support documents prepared for this action are included. See the support documents cited for each PFAS (also available in the rule docket) for more detailed information. Listing support documents created specifically for this rulemaking were developed with the TRI listing criteria in mind and are not intended to be used for purposes

beyond this rulemaking. These support documents underwent review by at least three EPA scientists, one from the TRI program within the OCSPP, one from the Office of Research and Development (ORD), and one from the Office of Land and Emergency Management (OLEM). Additionally, review often included multiple additional scientists from the same office, and relevant assessments were also reviewed by scientists in the Office of Water (OW). The Agency is soliciting comment on its proposed determinations that there is sufficient evidence to establish that one or more of the criteria for listing under EPCRA section 313(d)(2) have been met.

Additionally, EPA is proposing to use the following Agency databases that have evaluated and summarized hazard and dose-response literature as a basis for listing additional PFAS: EPA HAWC PFAS 150 (2022) project and ECOTOX, as described in Unit II.B. For such proposed listings, the Agency is not producing separate listing support documents, but rather is relying on its technical expertise to review and describe data provided in these databases as providing sufficient evidence, based on scientific principles, to support such listings (*i.e.*, these databases provide data on what toxicological effects are described by studies and at what doses). EPA considers this approach a more efficient means of informing additions to the TRI chemical list and solicits comment on this approach. Given that this would constitute a shift in relying on interpretation of extracted and curated data in a knowledge delivery platform (such as ECOTOX and projects in EPA HAWC) rather than a formal listing support document for TRI listing purposes, the Agency is soliciting comment on this approach before expanding its use for future listings. EPA notes that whether it generates a listing support document or relies on a formal hazard assessment, or it relies on interpreting curated data provided by a platform such as ECOTOX or projects in EPA HAWC, that it will review and describe the toxicity information so as to justify its finding of sufficient evidence to support a EPCRA 313(d)(2) listing criteria finding.

Unit III.B. lists the PFAS categories proposed for listing, along with the relevant EPCRA section 313(d) listing criterion/criteria. Unit III.C. lists the individual PFAS that EPA is proposing to list under this action as well as the statutory basis (as provided for the PFAS categories) for doing so.

A. Which PFAS identified in section 7321(d)(A) through (N) are not proposed for listing?

As noted in Unit II., the NDAA directed EPA to consider whether specific PFAS meet the EPCRA 313 listing criteria. Of the 39 unique PFAS identified in section 7321(d)(A) through (N) (*i.e.*, either by chemical identifier or by virtue of its inclusion in a validated drinking water analytical method), 13 PFAS have already been added to the TRI list pursuant to NDAA section 7321(b)(1) or 7321(c)(1); therefore, these chemicals need not be considered for listing in this action. EPA then reviewed available information on the remaining 26 PFAS identified in (A) through (N) to determine whether an EPCRA 313 listing was warranted, finding that nine of those PFAS meet the EPCRA 313 listing criteria (including as part of a category). Therefore, 17 PFAS are not being proposed for listing on the TRI chemical list at this time (*i.e.*, the chemicals specified in NDAA section 7321(d)(A) through (N) that are not included in this proposed action) are as follows, listed in order of inclusion under NDAA section 7321(d), with an explanation for why they are not being proposed with this action:

- NDAA section 7321(d)(2)(B): 2,3,3,3-Tetrafluoro 2-(1,1,2,3,3,3-hexafluoro)-2-(trifluoromethoxy) propanoyl fluoride (CASRN 2479-75-6) and (C): 2,3,3,3-Tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(trifluoromethoxy)propoxy]propanoic acid (CASRN 2479-73-4).

Following the process described in Unit III.B., EPA did not locate literature that would support a listing for these chemicals, thus EPA is not proposing the addition of these chemicals.

- NDAA section 7321(d)(2)(D): 4,8-dioxa-3H-perfluorononanoic acid – NDAA (ADONA) (CASRN 919005-14-4) and NDAA section 7321(d)(2)I (its 3 salts): ammonium 4,8-

dioxa-3H-perfluorononanoate (CASRN 958445-44-8), sodium 4,8-dioxa-3H-perfluorononanoate (NOCAS 892452; CASRN 2250081-67-3), potassium 2,2,3-trifluoro-3-[1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy]propanoate (CASRN 1087271-46-2): Following the process described in Unit III.B., EPA concluded that there were very limited results for ADONA and its salts, which were insufficient to support listing on the TRI.

- NDAA section 7321(d)(2)(M): Perfluoroheptanoic acid (PFHpA) (CASRN 375-85-9): Following the process described in Unit III.B., EPA identified potentially relevant literature evaluating human health effects of PFHpA. EPA has identified this chemical for further evaluation in future actions.

- NDAA section 7321(d)(2)(N): Of the PFAS for which a method to measure levels in drinking water has been validated by EPA, EPA did not identify data to support a listing based on EPCRA criteria for the following-listed PFAS:

- Perfluoro(2-ethoxyethane)sulfonic acid (PFEEESA) (CASRN 113507-82-7): Following the process described in Unit III.B., EPA did not locate results that would support a listing, thus EPA is not proposing the addition of this chemical.

- Nonfluoro-3,6-dioxaheptanoic acid (NFDHA) (CASRN 151772-58-6): Following the process described in Unit III.B., EPA did not locate results that would support a listing, thus EPA is not proposing the addition of this chemical.

- N-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA) (CASRN 2355-31-9): Following the process described in Unit III.B., EPA concluded that that there were very limited results for NMeFOSAA and its salts, which were unlikely to be sufficient for listing on the TRI. available data did not support a listing based on EPCRA criteria.

- Perfluoropentanoic acid (PFPeA) (CASRN 2706-90-3): Following the process

described in Unit III.B., EPA concluded that that there were very limited results for PFPeA and its salts, which were unlikely to be sufficient for listing on the TRI. available data did not support a listing based on EPCRA criteria.

- Perfluoropentanesulfonic acid (PFPeS) (CASRN 2706-91-4): Following the process described in Unit III.B., EPA concluded that that there were very limited results for PFPeS and its salts, which were unlikely to be sufficient for listing on the TRI. available data did not support a listing based on EPCRA criteria.

- N-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA) (CASRN 2991-50-6): Following the process described in Unit III.B., EPA concluded that that there were very limited results for NEtFOSAA and its salts, which were unlikely to be sufficient for listing on the TRI. available data did not support a listing based on EPCRA criteria. However, note that we are requesting comment on this chemical as a precursor to PFOS (see Unit VII.I).

- Perfluoroheptanesulfonic acid (PFHpS) (CASRN 375-92-8): Following the process described in Unit III.B., EPA concluded that available data did not support a listing based on EPCRA criteria. However, EPA did locate more data on this chemical than it did for the other chemicals in this list. A summary of EPA's findings on PFHpS is available in the docket (Ref. 17).

- 1H,1H, 2H, 2H-Perfluorodecane sulfonic acid (8:2FTS) (CASRN 39108-34-4): Following the process described in Unit III.B., EPA concluded that that there were very limited results for 8:2FTS and its salts, which were unlikely to be sufficient for listing on the TRI. available data did not support a listing based on EPCRA criteria. Note that we are requesting comment on this chemical as a precursor to PFOA (see Unit VIII.).

- 1H,1H, 2H, 2H-Perfluorohexane sulfonic acid (4:2FTS) (CASRN 757124-72-4):

Following the process described in Unit III.B., EPA did not locate results that would support a listing; thus, EPA is not proposing the addition of this chemical.

- Perfluoro-4-methoxybutanoic acid (PFMBA) (CASRN 863090-89-5): Following the process described in Unit III.B., EPA concluded that that there were very limited results for PFMBA and its salts, which were unlikely to be sufficient for listing on the TRI. Available data did not support a listing based on EPCRA criteria.

Additionally, one of the 18 PFAS that is identified in NDAA section 7321(d)(2) that is already on the TRI list is being proposed to be changed from an individual listing to being incorporated into a category.

- NDAA section 7321(d)(2)(I): Perfluorobutanesulfonate (CASRN 45187-15-3): This chemical is already on the TRI list; we are proposing it for removal as an individually-listed chemical because it is an anion for which reporting will occur based on the associated acid, perfluorobutanesulfonic acid (PFBS) (CASRN 375-73-5) see Unit II.C. for further discussion on the proposed removal of [an]ions.

B. What are the proposed chemical categories?

This unit identifies the PFAS categories that are included in this proposed action. For a discussion on reporting for categories, please see Unit IV.

For each of the proposed categories, EPA is including the acid and the associated salts, acyl/sulfonyl halides (where relevant), and anhydride (where relevant). Because the salts will dissociate under normal environmental conditions (Ref. 18) and the acyl/sulfonyl halides and anhydride will be converted to the acid in aqueous solutions (Ref. 19), EPA posits that these other forms of the PFAS would be expected to have toxicity profiles comparable to the acid and could be anticipated to become the same primary chemical of the category (the PFAS acid) once in the environment. Given the general chemical relationship amongst the salts, acyl/sulfonyl

halides, anhydride, and acid, such groupings of chemicals should therefore be reported to TRI as a chemical category.

For example, 9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS) (CASRN 756426-58-1) is the acid of the proposed category including 9Cl-PF3ONS itself, as well as its associated salt, potassium 9-chlorohexadecafluoro-3-oxanonane-1-sulfonate (CASRN 73606-19-6). Note that some categories include PFAS that are currently on the TRI list, but which EPA is proposing to categorize together as acid and salts. A discussion for each proposed chemical category and its EPCRA listing justification(s) follow the bulleted list. An “*” indicates that the parent compound is already on TRI; the parent compound is being listed here as a proposal to extend the given listing to associated salts, acyl/sulfonyl halides, and anhydride as part of a chemical category.

The scopes of these particular PFAS categories are specific to the needs of the TRI reporting program and may not be identical to other potential categorizations or classifications for other EPA purposes. Further, the TRI PFAS categories are separate from ongoing efforts by EPA and others to define PFAS categories or “classes” for purposes of other regulatory activities as well as for research.

The following are the list of chemical categories and reason for inclusion (For TRI Reporting):

- 9-Chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS) (CASRN 756426-58-1), Salts, and Sulfonyl Halides Category, which is based on EPCRA 313(d)(2)(B) (Chronic Human Health) and 313(d)(2)(C) (Effect on the Environment);

- 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS) (CASRN 763051-92-9), Salts, and Sulfonyl Halides Category, which is based on EPCRA 313(d)(2)(C) (Effect on the Environment);

- Hexafluoropropylene oxide dimer acid (HFPO-DA, GenX) (CASRN 13252-13-6)*, Salts, and Acyl Halides Category, which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);
- Perfluorobutanesulfonic acid (PFBS), Salts, Sulfonyl Halides, and Anhydride Category (CASRN 375-73-5)*, which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);
- Perfluorobutanoic acid (PFBA) (CASRN 375-22-4)*, Salts, Acyl Halides, and Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorodecanoic acid (PFDA) (CASRN 335-76-2)*, Salts, Acyl Halides, and Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorododecanoic acid (PFDoA) (CASRN 307-55-1)*, Salts, Acyl Halides, and Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorohexanesulfonic acid (PFHxS) (CASRN 355-46-4)*, Salts, Sulfonyl Halides, and Anhydride Category; which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorohexanoic acid (PFHxA) (CASRN 307-24-4)*, Salts, Acyl Halides, and Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorononanoic acid (PFNA) (CASRN 375-95-1)*, Salts, Acyl Halides, and Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health);
- 1*H*,1*H*,2*H*,2*H*-Perfluorooctane sulfonic acid (6:2 FTS) (CASRN 27619-97-2), Salts, and Sulfonyl Halides Category, which based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorooctanoic acid (PFOA) (CASRN 335-67-1)*, Salts, Acyl Halides, and Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluorooctanesulfonic acid (PFOS) (CASRN 1763-23-1)*, Salts, Sulfonyl Halides, and Anhydride Category; which is based on 313(d)(2)(B) (Chronic Human Health);
- Perfluoropropanoic acid (PFPrA) (CASRN 422-64-0), Salts, Acyl Halides, and

Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health); and

- Perfluoroundecanoic acid (PFUnA) (CASRN 2058-94-8), Salts, Acyl Halides, and

Anhydride Category, which is based on 313(d)(2)(B) (Chronic Human Health).

The Agency has provided important endpoints in the following summary. For the full toxicological profile, please refer to the respective references.

1. *9-Chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS) (CASRN 756426-58-1), Salts, Sulfonyl Halides, and Anhydride Category.*

a. *Human health hazard assessment.* This category would include all associated salts and sulfonyl halides including: potassium 9-chlorohexadecafluoro-3-oxanonane-1-sulfonate (CASRN 73606-19-6). EPA found evidence of both serious or irreversible human health effects and environmental effects due to 9Cl-PF3ONS and its salts. EPA is proposing to list 9Cl-PF3ONS and any associated salts and sulfonyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the sulfonyl halides would be expected to be converted to 9Cl-PF3ONS in aqueous solutions. Therefore, the toxicity concerns for 9Cl-PF3ONS apply to all members in this category.

Available animal data, along with supporting mechanistic data, indicate that the most sensitive targets of oral toxicity of 9Cl-PF3ONS are the liver and thyroid. Observations in available subchronic oral studies indicate that 9Cl-PF3ONS is hepatotoxic: In a 10-week drinking water study in female mice, increases in serum enzymes (*e.g.*, ALT, AST), liver weights, and incidence of histopathological foci indicative of altered tissue architecture (*e.g.*, hepatocytic vacuolization and ballooning) were observed at a lowest observed adverse effect level (LOAEL) of 0.003 mg/kg/day.

A similar profile of liver injury was observed in a 56-day gavage study in male mice. Significant increases in liver weights and histopathological foci (*e.g.*, focal inflammation, lipid

droplets) were observed at a LOAEL of 0.2 mg/kg/day. At the next highest administered dose (0.9 mg/kg/day), serum ALT and ALP levels were elevated 3-fold and 11-fold, respectively, and histopathological lesions indicated more severe foci of cellular injury (e.g., hepatocellular necrosis).

In a 28-day subchronic study in rats, it was also determined that 9Cl-PF3ONS had adverse effects on thyroid hormone economy (Ref. 20). Decreased serum T4 and T3 levels in males and females and thyroid follicular hyperplasia in females were observed at ≥ 19 mg 9Cl-PF3ONS/kg-day. Mechanistic studies support that 9Cl-PF3ONS could disrupt thyroid hormone homeostasis via direct binding to thyroid hormone receptors and the carrier protein transthyretin. Additionally, alterations in thyroid hormone levels and genes involved in the hypothalamic-pituitary-thyroid (HPT) axis were observed in zebrafish larva exposed to potassium 9Cl-PF3ONS.

Lastly, another study used a population-based, quantitative *in vitro* to *in vivo* extrapolation approach and determined that 9Cl-PF3ONS disturbed lipid homeostasis in HepG2 cells (human hepatoma cell line used for *in vitro* hepatotoxicity studies) through enhancement of lipid accumulation and fatty acid β -oxidation (Ref. 20).

b. *Ecological hazard assessment.* Several studies that evaluated sub-lethal endpoints indicate that 9Cl-PF3ONS and its potassium salt can cause adverse health effects at very low concentrations. A multi-generation chronic study with 180-day exposure of sexually mature 5-month-old zebrafish identified a lowest effect concentration (LOEC) of 0.005 mg/L for effects on growth, reproduction, and development; a NOEC was not identified; and, therefore, a maximal acceptable toxicant concentration (MATC) value could not be calculated.

In another study with zebrafish (28-day exposure) the calculated aquatic chronic MATC value for hepatic effects was 0.032 mg/L. Additionally, several studies have reported the effects

of 9Cl-PF3ONS and its potassium salt on thyroid hormone disruption in fish. One study reported increased thyroxine (T4) but not 3,5,30-triiodothyronine (T3) in zebrafish embryos following 5-day exposure to F-53B, the primary component of which is 9Cl-PF3ONS. The authors also conducted an *in silico* molecular docking analysis and F-53B was found to fit into the binding pocket of zebrafish thyroid transport protein (TTR) in the correct orientation, and to form three hydrogen bonds.

Another study found that chronic F-53B exposure in adult zebrafish increased T4 levels, decreased T3 levels and exhibited transgenerational thyroid hormone disrupting effects. In a chronic toxicity test with chinese rare minnow, whole body total and free 3,5,30-triiodothyronine (T3) levels were significantly increased following exposure to F-53B for 4 weeks. Together, these studies indicate that 9Cl-PF3ONS and its potassium salt have the potential to cause thyroid hormone disruption effects (Ref. 21).

There is substantive evidence that 9Cl-PF3ONS has the potential to bioaccumulate in organisms. The tissue specific kinetic bioconcentration factor (BCF) reported in one study ranged from 228-2212 for female zebrafish and 473-4425 for male zebrafish, at 10 and 100 µg/l exposures. In another study by the same authors, the reported whole body kinetic BCF was 3,612 at the nominal 10 µg/l exposure and 3,615 at the nominal 100 µg/l exposure. Several observational studies have reported the detection of F-53B in aquatic organisms (Ref. 21).

c. *Conclusion.* EPA believes there is sufficient evidence to list the 9Cl-PF3ONS, Salts, Sulfonyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible adverse liver and thyroid effects of this substance, and pursuant to section 313(d)(2)(C)(iii) for its environmental toxicity and bioaccumulation.

2. *11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS) (CASRN 763051-92-9), Salts, Sulfonyl Halides, and Anhydride Category.*

This category would include all associated salts and sulfonyl halides including: potassium 11-chloroeicosafluoro-3-oxaundecane-1-sulfonate (CASRN 83329-89-9). EPA found evidence of serious environmental effects of 11Cl-PF3OUdS and its salts and sulfonyl halides. EPA is proposing to list 11Cl-PF3OUdS and its associated salts, sulfonyl halides, and anhydride as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the sulfonyl halides would be expected to be converted to 11Cl-PF3OUdS in aqueous solutions. Therefore, the toxicity concerns for 11Cl-PF3OUdS apply to all members in this category.

a. *Ecological hazard assessment.* 11 cL-PF3OUds showed a lethal effect in zebrafish larvae after a 7-day exposure [$LC_{50} \leq 0.8$ mg/L ~ 0.8 ppm]. This value has been calculated by the conversion of ~ 1.2 μ M which was obtained from the linear dose-response curve for 11cl-PF3OUdS. This nominal LC_{50} of 0.8 mg/L suggests moderate to high concern for hazard upon acute exposure of aquatic organisms (*i.e.*, fish) to 11cl-PF3OUdS, especially given that actual concentrations were likely lower than nominal (Ref. 22).

Persistence in the environment is expected to be high for 11cl-PF3OUdS and its potassium salt. In an aerobic biodegradation study using loam surface soils with $\sim 22\%$ moisture content at 24°C, negligible degradation of 11cl-PF3OUdS was observed after 105 days (Ref. 22).

Available data suggest that 11cl-PF3OUdS may bioaccumulate significantly in aquatic species [*e.g.*, a whole-body BCF of 9,800 L/kg* and whole-body bioaccumulation factor (BAF) of 14,000 L/kg was determined for 11cl-PF3OUdS in the experimental studies of Chinese rare minnows and black-spotted frogs, respectively. *Note that for the study with the Chinese rare minnows, animals were exposed to the mixture F-53B, of which 11cl-PF3OUdS is a component. BCF (protein) was also determined to be 58,000 L/Kg (average) for 11cl-PF3OUdS in the experimental studies for rainbow trout] (Ref. 22).

b. *Conclusion.* EPA believes there is sufficient evidence to list the 11cl-PF3OUdS, Salts,

Sulfonyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313I)(d)(2)(C) for (iii) its toxicity and tendency to bioaccumulate in the environment data for this chemical.

3. *Hexafluoropropylene oxide dimer acid (HFPO-DA; Gen X) (CAS 13252-13-6), Salts, and Acyl Halides Category.*

This category would include all associated salts and acyl halides including: propanoyl fluoride, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-] (HFPO-DAF) (CASRN 2062-98-8), ammonium perfluoro-2-methyl-3-oxahexanoate (also known as and currently TRI-listed as hexafluoropropylene oxide dimer acid (HFPO-DA) ammonium salt) (CASRN 62037-80-3), potassium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (CASRN 67118-55-2) and sodium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (CASRN 67963-75-1).

HFPO-DA was added to the TRI list automatically in January 2020 pursuant to NDAA section 7321(b)(1)(F). EPA is proposing to list HFPO-DA and its associated salts and acyl halides as a single TRI category, as the salts would dissociate in aqueous solutions and the acyl halides would be expected to be converted to HFPO-DA in aqueous solutions. Therefore, the toxicity concerns apply to all members in this category.

a. *Human health hazard assessment.* A 2021 EPA human health assessment exists for HFPO-DA and its ammonium salt (*i.e.*, GenX chemicals). Based on the available data, the liver was identified as the most sensitive target of HFPO-DA toxicity and a subchronic reference dose (RfD) of 3×10^{-5} mg/kg bw-day and a chronic RfD of 3×10^{-6} mg/kg bw-day was derived (Ref. 23).

Other effects observed in rats and/or mice following HFPO-DA exposure included kidney toxicity (*e.g.*, increased relative kidney weight), immune effects (*e.g.*, antibody suppression), hematological effects (*e.g.*, decreased red blood cell count, hemoglobin, and hematocrit), reproductive/developmental effects (*e.g.*, increased early deliveries, placental

lesions, changes in maternal gestational weight gain, and delays in genital development in offspring), and cancer (*e.g.*, liver and pancreatic)) (Ref. 23). There is *Suggestive Evidence of Carcinogenic Potential* in humans for the oral route of exposure (Ref. 23).

b. *Conclusion.* EPA believes there is sufficient evidence to list the HFPO-DA, Salts, and Acyl Halides category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii) for serious or irreversible reproductive dysfunctions and other chronic effects on the liver, development, hematological system, and immune system after oral exposure.

4. **Perfluorobutanesulfonic acid (PFBS) (375-73-5), Salts, Sulfonyl Halides, and Anhydride Category.*

This category would include all associated salts, sulfonyl halides, and anhydride including: perfluorobutanesulfonyl fluoride (CASRN 375-72-4), potassium perfluorobutane sulfonate (CASRN 29420-49-3), perfluorobutanesulfonic anhydride (CASRN 36913-91-4), sodium nonafluorobutane-1-sulfonate (CASRN 60453-92-1), ammonium perfluorobutanesulfonate (CASRN 68259-10-9), bis(2-hydroxyethyl)ammonium perfluorobutanesulfonate (CASRN 70225-18-2), lithium nonafluorobutane-1-sulfonate (CASRN 131651-65-5), tetrabutylphosphonium perfluorobutanesulfonate (CASRN 220689-12-3) and magnesium nonafluorobutanesulfonate (CASRN 507453-86-3). This category does not include ionic forms such as perfluorobutanesulfonate (CASRN 45187-15-3), though any conversion of those ions into PFBS or associated salts would constitute manufacturing for purposes of EPCRA section 313 and must be considered towards the PFBS, Salts, Sulfonyl Halides, and Anhydride category reporting threshold. If the PFAS category reporting threshold is met, then the facility's releases and other waste activities for this category will include those of the ion. In April 2021, EPA published final human health toxicity values for PFBS and the related compound potassium perfluorobutanesulfonate (CASRN 29420-49-3) (Ref. 24) therefore, these chemicals have

already been added to the TRI chemical list pursuant to NDAA section 7321(c). EPA is now proposing to list PFBS, its associated salts, sulfonyl halides, and anhydride as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the sulfonyl halides and anhydride would be expected to be converted to PFBS in aqueous solutions. Therefore, the toxicity concerns for PFBS apply to all members in this category.

a. *Human health hazard assessment.* Health outcomes evaluated across available studies included effects on the thyroid and developing offspring following oral exposure to PFBS. There was a small number of epidemiology studies per outcome, which had limitations including poor sensitivity resulting from low exposure levels. Similar patterns of decreases in thyroid hormones (*i.e.*, total T3, total T4, and free T4) were observed in PFBS-exposed pregnant mice and gestationally exposed female mouse offspring at ≥ 200 mg/kg-d and in nonpregnant adult female and adult male rats at ≥ 62.6 mg/kg-d. These decreases were statistically significant ($\sim 20\%$ in dams and $\sim 50\%$ in offspring), were shown to persist at least 60 days after gestational exposure in offspring and exhibited dose dependence (Ref. 24).

In the only mouse developmental study, developmental effects and altered markers of female reproductive development or function were observed in female offspring after gestational PFBS exposure, including decreased body weight, delayed eye opening, delayed vaginal opening, altered estrous cyclicity (including prolonged diestrus), altered reproductive hormones (*e.g.*, decreased estradiol and progesterone), and effects on reproductive organs (*e.g.*, weight and ovarian morphology). Most effects were observed at ≥ 200 mg/kg-d, with several changes noted at PND 60. Endpoints relating to pregnancy, survival, and fetal morphological alterations were unchanged in both rats and mice and endpoints relating to fertility were unchanged in parental rats and mice across the four available studies. Alterations in histopathological markers of fertility were observed in mouse offspring, though the reproductive function of those offspring

was not tested. In other studies, developmental body weight changes in rat offspring were either unchanged or observed only at doses causing parental toxicity (Ref. 24).

The PFBS toxicity assessment derived subchronic and chronic oral RfDs of 0.0009 mg/kg-day and 0.0003 mg/kg-day, respectively, based on thyroid effects (Ref. 24).

EPA found that PFBS and its associated salts are known to cause or reasonably anticipated to cause serious or irreversible chronic health effects to the thyroid, and to have serious or irreversible reproductive/developmental effects.

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFBS, Salts, Sulfonyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible thyroid toxicity and reproductive/developmental effects.

5. **Perfluorobutanoic acid (PFBA) (CASRN 375-22-4), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including: perfluorobutanoyl fluoride (CASRN 335-42-2), perfluorobutanoic anhydride (CASRN 336-59-4), heptafluorobutryl chloride (CASRN 375-16-6), sodium perfluorobutanoate (CASRN 2218-54-4), potassium perfluorobutanoate (CASRN 2966-54-3), silver heptafluorobutyrate (CASRN 3794-64-7), ammonium perfluorobutanoate (CASRN 10495-86-0), rhodium(II) perfluorobutyrate dimer (CASRN 73755-28-9). This category does not include ionic forms such as perfluorobutanoate (CASRN 45048-62-2), though any conversion of those ions into PFBA or associated salts (including via dissociation in aqueous solution) would constitute manufacturing for purposes of EPCRA section 313 and must be considered towards the PFBA, Salts, Acyl Halides, and Anhydride category reporting threshold.

In December 2022, EPA published an IRIS assessment for PFBA and associated salts (CASRN 10495-86-0, 2218-54-4, 2966-54-3, 45048-62-2) (Ref. 25); therefore, these chemicals

have already been added to the TRI chemical list pursuant to NDAA section 7321(c). EPA is now proposing to list PFBA and its associated salts as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFBA in aqueous solutions. This rule is also proposing to add silver heptafluorobutyrate (CASRN 3794-64-7) to TRI as part of this category. While the IRIS assessment did not necessarily extend to non-alkali metal salts such as silver heptafluorobutyrate due to PFBA-independent toxicity contributors, the overall compound has at least the same toxicity of the associated acid, PFBA. The toxicity concerns for PFBA that support a TRI listing apply to all members in this category.

a. *Human health hazard assessment.* The currently available evidence indicates hazards likely exist with respect to the potential for thyroid, liver, and developmental effects in humans, given sufficient PFBA exposure conditions. These judgments are based on data from short-term (28-day exposure), subchronic (90-day exposure), and developmental (17-day gestational exposure) oral-exposure studies in rodents (Ref. 25).

A consistent and coherent pattern of thyroid effects including hormonal, organ weight, and histopathological changes were observed, generally at PFBA exposure levels ≥ 30 mg/kg-day, although some notable effects were observed at 6 mg/kg-day. Consistent, dose-dependent decreases in total and free T4 were observed independent of any effect on TSH. Additionally, increased thyroid weights and increases in thyroid follicular hypertrophy were observed. Because of the similarities in the production and regulation of thyroid hormone homeostasis between rodents and humans, the effects in rodents were considered relevant to humans (Ref. 25).

Across various studies, liver effects were generally seen at PFBA exposure levels ≥ 30 mg/kg-day. The PFBA-induced effects were observed in two species (rats and mice), in males and females, and across multiple exposure durations (short-term, subchronic, and gestational).

Consistent, coherent, dose-dependent, and biologically plausible effects were observed for increased liver weights and increased incidences of hepatic histopathological lesions. Supporting the biological plausibility and human relevance of these effects is mechanistic information that suggests non- peroxisome proliferator-activated receptor alpha (PPAR α) mode of actions (MOAs) could explain some of the observed effects in exposed rodents and that observed effects might be precursors to clearly adverse health outcomes such as steatosis (Ref. 25).

PFBA exposure caused delays in developmental milestones (days to eye opening and vaginal opening) without effects on fetal (pup) growth at ≥ 175 mg/kg-day. The results demonstrate a constellation of effects affecting the developing organism that is internally coherent (within-study) and consistent across related PFAS compounds, including PFBS, PFOA, and PFOS. These developmental effects are considered relevant to humans (Ref. 25).

Based on liver and thyroid effects, the PFBA toxicity assessment derived an overall RfD of 1×10^{-3} mg/kg-day.

EPA found that PFBA and its associated salts are known to cause or can reasonably be anticipated to cause serious or irreversible chronic health effects to both endocrine and hepatic systems. The IRIS assessment found increased hepatocellular hypertrophy (liver), as well as decreased total T4 (thyroid). Available evidence also indicates that PFBA exposure during pregnancy or *in utero* likely causes developmental effects.

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFBA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible endocrine, liver, and thyroid effects.

6. **Perfluorodecanoic acid (PFDA) (CASRN 335-76-2), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including:

perfluorodecanoyl chloride (CASRN 307-38-0), ammonium perfluorodecanoate (CASRN 3108-42-7), sodium perfluorodecanoate (CASRN 3830-45-3), and perfluorodecanoic anhydride (CASRN 942199-24-8).

PFDA was added to the TRI list automatically in January 2020 pursuant to NDAA section 7321(b)(1)(E). In July 2024, EPA published an IRIS assessment for PFDA and associated salts (CASRNs 3108-42-7 and 3830-45-3), thereby causing these specific salts to be added to the TRI chemical list pursuant to NDAA section 7321(c). EPA is proposing to list PFDA and its associated salts and acyl halides as a single TRI category, as the salts are expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFDA in aqueous solutions. Therefore, the toxicity concerns of PFDA apply to all members in this category.

a. *Human health hazard assessment.* In July 2024, EPA finalized its IRIS assessment for PFDA and related salts (ammonium perfluorodecanoate (PFDA NH₄, CASRN 3108-42-7) and sodium perfluorodecanoate (PFDA-Na, CASRN 3830-45-3)) (Ref. 26). Overall, the available evidence indicates that PFDA exposure is likely to cause liver, immune, developmental, and male and female reproductive effects in humans, given sufficient exposure conditions. The review concludes that the available evidence indicates PFDA exposure is likely to cause adverse liver effects in humans based on concordant effects for increased liver weight, alterations in levels of serum biomarkers of liver injury (ALT, AST, ALP, bile salts/acids, bilirubin and blood proteins), and some evidence of hepatocyte degenerative or necrotic changes that provide support for the adversity of PFDA-induced liver toxicity reported in rats and mice exposed to PFDA doses ≥ 0.156 mg/kg-day (Ref. 26).

The hazard identification judgement that PFDA exposure is likely to cause immunotoxicity, specifically immunosuppression, in humans, is based primarily on consistent

evidence of reduced antibody responses from human epidemiological studies (three studies in children and one in adults) at levels of 0.3 ng/mL (median exposure in studies observing an adverse effect. Reduced antibody response is an indication of immunosuppression and may result in increased susceptibility to infectious disease (Ref. 27). The antibody results present a consistent pattern of findings that higher prenatal, childhood, and adult serum concentrations of PFDA were associated with suppression of at least one measure of the antivaccine antibody response to common vaccines in two well-conducted birth cohorts in the Faroe Islands and supported by a low confidence study in adults. An inverse association was observed in 21 of 26 evaluations, with a minimum of a 2% decrease in antibody concentration per doubling of PFDA concentration at levels consistent with the general population in NHANES; six of these evaluations were statistically significant and exhibited a large magnitude of effect (*i.e.*, >18% decrease in response). These associations were observed despite poor study sensitivity, which increases confidence in the findings (Ref. 26). Additionally, the results are consistent with evidence of an association between exposure to PFOS and PFOA and reduced antibody responses in human studies indicative of potential immunosuppression (Ref. 28, 29).

PFDA is likely to cause developmental toxicity in humans. This conclusion is based on dose-dependent decreases in fetal weight in mice gestationally exposed to PFDA at doses ≥ 0.5 mg/kg-day, and is further supported by evidence of decreased birth and childhood weight from studies of exposed humans in which PFDA was measured during pregnancy, primarily with median PFDA values ranging from 0.11 to 0.46 ng/mL. This conclusion is further supported by coherent epidemiological evidence for biologically related effects (*e.g.*, decreased postnatal growth and birth length) (Ref. 26).

A 28-day study in rats indicated that PFDA exposure is likely to cause adverse effects to the male reproductive system, based on alterations in sperm counts, testosterone levels, and male

reproductive histopathology and organ weights at doses ≥ 0.625 mg/kg-day. In the same study, PFDA was shown to decrease the number of days spent in estrus and increase the amount of time spent in diestrus in female rats at ≥ 1.25 mg/kg-day. A continuous state of diestrus started at Day 21 in female rats exposed to 2.5 mg/kg-day. *In vitro* and intraperitoneal studies corroborate the effects seen in male rodents and suggest that PFDA disrupts Leydig cell function, resulting in reduced steroidogenesis and testosterone (Ref. 26).

The Agency derived a lifetime and subchronic oral RfD for noncancer effects of 2×10^{-9} mg/kg-day based on immune and developmental effects (Ref. 26).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFDA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B) for serious or irreversible reproductive dysfunctions and other chronic effects on the liver, development, and immune system.

7. **Perfluorododecanoic acid (PFDoA) (CASRN 307-55-1), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including: ammonium tricosafuorododecanoate (CASRN 3793-74-6) and perfluorododecanoic anhydride (CASRN 1456735-80-0). PFDoA was added to the TRI list automatically in January 2020 pursuant to NDAA section 7321(b)(1)(E). EPA is proposing to list PFDoA and its associated salts and acyl halides as a single TRI category, as the salts are expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFDoA in aqueous solutions. Therefore, the toxicity concerns of PFDoA apply to all members in this category.

a. *Human health hazard assessment.* Available animal data indicate that the most sensitive target of oral toxicity of PFDoA in rats is the liver, with a systemic NOAEL of 0.1 mg/kg-day and a LOAEL of 0.5 mg/kg-day based on increased liver weights in males and

females. Toxicity to both the male and female reproductive systems has been observed in rats following oral exposure to PFDoA, including changes in serum hormone levels, histopathological changes in reproductive organs (various histopathological lesions were observed in the reproductive organs of male rats exposed to 2.5 mg/kg-day for 42 days (starting 14 days prior to mating)), and alterations in estrous cyclicity in female rats, with the most sensitive changes observed at doses as low as 0.2 mg/kg-day. The majority of female rats exposed to 2.5 mg/kg-day could not maintain a pregnancy with most dying due to pregnancy and/or delivery complications prior to scheduled sacrifice. Gestation and delivery indices were significantly lower at 2.5 mg/kg-day, with only 1/3 of the surviving dams delivering live pups. In female reproductive organs, hemorrhage of the implantation site and/or congestion in the endometrium were detected in the uterus of all 7 females found dead or moribund at the end of the gestation period. Hemorrhage at the implantation site was also found in one female that did not deliver live pups (all pups were stillborn). In one litter, the number of normally delivered pups in the 2.5 mg/kg-day group was 16; however, two of them were found dead on nursing day 0. Although the other 14 pups survived to the end of the study, their body weights on PNDs 0, 1, and 4 were markedly lower than those of the control group. Body weight in females in the main group was significantly decreased at 2.5 mg/kg/day through the gestation period (Ref. 30).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFDoA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(I) and (IV) for serious or irreversible reproductive dysfunctions and liver effects.

8. **Perfluorohexanesulfonic acid (PFHxS) (CASRN 355-46-4), Salts, Sulfonyl Halides, and Anhydride Category.*

This category would include all associated salts and sulfonyl halides including: perfluorohexanesulfonyl fluoride (CASRN 423-50-7), potassium perfluorohexanesulfonate

(CASRN 3871-99-6) (currently TRI-listed as “1-hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt”), lithium perfluorohexanesulfonate (CASRN 55120-77-9), ammonium perfluorohexanesulfonate (CASRN 68259-08-5) (currently TRI-listed as “1-hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt”), bis(2-hydroxyethyl)ammonium perfluorohexanesulfonate (CASRN 70225-16-0) (currently TRI-listed as “1-hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, compd. with 2,2'-iminobis[ethanol] (1:1)”), sodium perfluorohexanesulfonate (CASRN 82382-12-5), and perfluorohexanesulfonic anhydride (CASRN 109065-55-6).

PFHxS was added to the TRI list automatically in January 2020 pursuant to NDAA section 7321(b)(1)(I). EPA is now proposing to list PFHxS and its associated salts and sulfonyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the sulfonyl halides would be expected to be converted to PFHxS in aqueous solutions. Therefore, the toxicity concerns for PFHxS apply to all members of this category.

In July 2023, a draft IRIS toxicological review for PFHxS and related salts (potassium perfluorohexanesulfonate (CASRN 3871-99-6), ammonium perfluorohexanesulfonate (CASRN 68259-08-5), and sodium perfluorohexanesulfonate (CASRN 82382-12-5), as well as nonmetal and alkali metal salts of PFHxS) was released for public comment and is currently undergoing external peer review (Ref. 31).

a. Human health hazard assessment. The draft IRIS assessment concludes that the evidence indicates PFHxS exposure is likely to cause immunotoxicity and thyroid toxicity in humans, given sufficient exposure conditions. The primary supporting evidence for immunotoxicity included consistent findings of decreased antibody responses to vaccination against tetanus or diphtheria in children (Ref. 31). The evidence for thyroid toxicity, specifically decreased thyroid hormones, is based primarily on a short-term study and two multigenerational

studies in rats reporting a consistent and coherent pattern of hormonal changes at PFHxS exposure levels ≥ 2.5 mg/kg-day. A consistent dose-dependent decrease of T4, and to a lesser extent T3, in adult and juvenile rats, with a magnitude of effect (up to 70%) in the absence of effects in TSH was observed (with males being more sensitive). In addition, one multigenerational study reported increased incidence of minimal thyroid hypertrophy and moderate hyperplasia in male rats after PFHxS exposure. Due to the similarities in thyroid hormone production between rodents and humans, the effects in rodents were considered relevant to humans (Ref. 31).

The Agency derived a lifetime and subchronic oral RfD for noncancer effects of 4×10^{-10} mg/kg-day based on immune effects (decreased serum anti-tetanus antibody concentration in children) (Ref. 31).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFHxS, Salts, Sulfonyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic effects on the thyroid and immune system.

9. *Perfluorohexanoic acid (PFHxA) (CASRN 307-24-4), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including: perfluorohexanoic anhydride (CASRN 308-13-4), silver perfluorohexanoate (CASRN 336-02-7), perfluorohexanoyl fluoride (CASRN 355-38-4), perfluorohexanoyl chloride (CASRN 335-53-5), sodium perfluorohexanoate (CASRN 2923-26-4), potassium undecafluorohexanoate (CASRN 3109-94-2), and ammonium perfluorohexanoate (CASRN 21615-47-4). In April 2023, EPA finalized a toxicity value for PFHxA and related salts (specifically, ammonium perfluorohexanoate and sodium perfluorohexanoate) (Ref. 32). Accordingly, PFHxA and those salts specified by CASRN were automatically added to the TRI chemical list as of January 1,

2024, pursuant to the NDAA section 7321(c)(1)(A)(i). EPA is now proposing to list PFHxA and its associated salts and acyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFHxA in aqueous solutions. This rule is also proposing to add non-alkali metals including silver perfluorohexanoate (CASRN 336-02-7) to this category. The IRIS assessment did not necessarily extend to non-alkali metal salts such as silver perfluorohexanoate. Due to PFHxA-independent toxicity contributors, the metal portion of the salt may present additional toxicity concerns (*e.g.*, a mercury salt would have additional toxicity concerns beyond any toxicity concerns associated with the acid due to the presence of mercury). However, the IRIS assessment does establish that the overall compound has at least the same toxicity of the associated acid. The toxicity concerns for PFHxA apply to all members in this category.

a. Human health hazard assessment. Overall, the available evidence indicates that PFHxA likely causes hepatic, developmental, hematopoietic, and thyroid-related endocrine effects in humans. Specifically, for hepatic effects, the primary support for this hazard conclusion included evidence of increased relative liver weights and increased incidence of hepatocellular hypertrophy in adult rats. These hepatic findings correlated with changes in clinical chemistry (*e.g.*, serum enzymes, blood proteins) and necrosis. Developmental effects were identified as a hazard based on evidence of decreased offspring body weight and increased perinatal mortality in exposed rats and mice. For hematopoietic effects, the primary supporting evidence included decreased red blood cell counts, decreased hematocrit values, and increased reticulocyte counts in adult rats. A 28-day study in rats showed a strong dose-dependent decrease in serum thyroid hormones in males. An overall RfD of 5×10^{-4} mg/kg-day was selected based on developmental effects (decreased postnatal body weight) and is considered protective of the other effects (Ref. 32).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFHxA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic effects on the liver, thyroid, hematopoietic system, and development.

10. *Perfluorononanoic acid (PFNA) (CASRN 375-95-1), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including: heptadecafluorononanoyl fluoride (CASRN 558-95-2), ammonium perfluorononanoate (CASRN 4149-60-4), potassium perfluorononanoate (CASRN 21049-38-7), sodium heptadecafluorononanoate (CASRN 21049-39-8), and heptadecafluorononanoyl chloride (CASRN 52447-23-1), and perfluorononanoic anhydride (CASRN 228407-54-3). PFNA has been on the TRI list since January 1, 2020, pursuant to NDAA section 7321(b)(1)(H). EPA is now proposing to list PFNA and its associated salts and acyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFNA in aqueous solutions. Therefore, the toxicity concerns for PFNA apply to all members in this category.

a. *Human Health Hazard Assessment.* In April 2024, EPA finalized a National Primary Drinking Water Rule (NPDWR) for PFOA and PFOS, as well as three other PFAS (PFNA, PFHxS and HFPO-DA) and mixtures of two or more of four PFAS (PFNA, PFHxS, HFPO-DA and PFBS); one of the PFAS covered in the NPDWR is PFNA (89 CFR 32532; April 26, 2024) (Ref. 33). In the final NPDWR, EPA cited associations between PFNA exposure and adverse hepatic effects and limited evidence for decreased antibody response in epidemiological studies (Ref. 4). The final NPDWR also noted that results of a 2023 meta-analysis suggest that decreases in birth weight are an adverse effect of PFNA exposure in humans (Ref. 34). In animal studies,

offspring of PFNA-exposed rodents had reduced bodyweights and survival, and delayed development (Ref. 4). ATSDR established an intermediate-duration oral minimal risk level (MRL) of 3×10^{-6} mg/kg/day for PFNA based on decreased body weight gain and developmental delays in mice born to mothers that were orally exposed to PFNA during gestation (with presumed continued indirect exposure of offspring via lactation) (Ref. 4). EPA concluded that studies on exposure to PFNA support adverse effects, including effects on development, reproduction, immune function, and the liver (Ref. 4, 33).

The draft IRIS assessment for PFNA (Ref. 35) supported the findings in the ATSDR toxicological profile and the NPDWR's conclusions that toxic endpoints were development, reproduction, and the liver, but stated that the evidence of immunotoxicity was only suggestive. The draft IRIS assessment indicated that there is robust epidemiological evidence that PFNA exposure is associated with deficits in birth weight, and that this finding is supported by coherent findings of postnatal growth restriction and to a lesser degree decreased birth length (Ref. 35). The overall lifetime oral RfD of 7×10^{-9} mg/kg-day was selected based on developmental effects (decreased birth weight) (Ref. 35).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFNA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(I) and (IV) for serious or irreversible reproductive dysfunctions and other chronic health effects in humans (including reproduction/development and liver effects).

11. *1H,1H, 2H, 2H-Perfluorooctane sulfonic acid (6:2 fluorotelomer sulfonic acid, 6:2 FTS) (CASRN 27619-97-2), Salts, Sulfonyl Halides, and Anhydride Category.*

This category would include all associated salts and sulfonyl halides including: 1H,1H,2H,2H-perfluorooctyl iodide (CASRN 2043-57-4), 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonyl chloride (CASRN 27619-89-2), sodium 3,3,4,4,5,5,6,6,7,7,8,8,8-

tridecafluorooctane-1-sulfonate (CASRN 27619-94-9), potassium 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonate (CASRN 59587-38-1), 6:2 fluorotelomer sulphonate ammonium (CASRN 59587-39-2) and 1-octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-, barium salt (2:1) (CASRN 1807944-82-6). EPA is proposing to list 6:2 FTS and its associated salts and sulfonyl halides as a single TRI category, as the salts are expected to dissociate in aqueous solutions and the sulfonyl halides would be expected to be converted to 6:2 FTS in aqueous solutions. Therefore, the toxicity concerns for 6:2 FTS apply to all members in this category.

a. *Human health hazard assessment.* EPA reviewed available literature in EPA HAWC for 6:2 FTS, as identified in Carlson *et al.*, (Ref. 14) and Radke *et al.* (Ref. 36) (PFAS 150 (2022) project). (For study details, see: <https://hawc.epa.gov/assessment/100500085/>.) A 28-day repeated-dose oral gavage study in male CD-1 mice by Sheng *et al.* (Ref. 37), which was evaluated as medium confidence for clinical chemistry and body/liver weights, found significant increases in absolute and relative liver weights relative to controls, with no effect on body weights. Serum levels of AST and albumin (ALB) were also significantly increased. Study results also qualitatively reported histopathological observations consistent with liver injury, including necrosis and hepatocellular hypertrophy. The effect size for increased liver weight is considered biologically significant (22% increase relative to controls).

Other studies included in the EPA HAWC PFAS 150 (2022) project (as supplemental studies) for 6:2 FTS include assessments summarized by the European Chemicals Agency (ECHA), describing mechanistic evidence and genotoxicity. ECHA assessed the genotoxicity of 6:2 FTS in *in vitro* and *in vivo* assays. Overall, 6:2 FTS was positive for inducing structural chromosomal aberrations in Chinese Hamster Ovary (CHO) cells but was negative in all other genotoxicity assays. Other mechanistic evidence suggests 6:2 FTS exposure induces inflammation, including in the liver, and disrupts liver gene expression. Sheng *et al.*, (Ref. 37)

reported increased cytokines in serum and liver (TNF α , IL β , IL-10), and increased expression of proteins indicative of an inflammatory response (IkBa, NFkB/p65, NRF-2, TRL-4, and TNFR-2) in male CD-1 mice after 28 days of oral exposure to 6:2 FTS at a dose of 5 mg/kg/day.

b. *Conclusion.* EPA believes there is sufficient evidence to list the 6:2 FTS, Salts, Sulfonyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(ii)(IV) for serious or irreversible chronic effects (including adverse liver and genotoxicity effects).

12. *Perfluorooctanoic acid (PFOA) (CASRN 335-67-1), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including: pentadecafluorooctanoyl chloride (CASRN 335-64-8), pentadecafluorooctanoyl fluoride (CASRN 335-66-0), silver perfluorooctanoate (CASRN 335-93-3) (currently TRI-listed as “silver(I) perfluorooctanoate”), sodium perfluorooctanoate (CASRN 335-95-5), potassium perfluorooctanoate (CASRN 2395-00-8), ammonium perfluorooctanoate (CASRN 3825-26-1), lithium perfluorooctanoate (CASRN 17125-58-5), cesium perfluorooctanoate (CASRN 17125-60-9), perfluorooctanoic anhydride (CASRN 33496-48-9), chromium perfluorooctanoate (CASRN 68141-02-6) (currently TRI-listed as chromium(III) perfluorooctanoate) and potassium pentadecafluorooctanoate—water (1:1:2) (CASRN 98065-31-7). In January 2020, PFOA and three of its salts were automatically added to the TRI chemical list as individual chemicals pursuant to the NDAA section 7321(b)(1)(A) and (B). EPA is now proposing to list PFOA and its associated salts and acyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFOA in aqueous solutions. Therefore, the toxicity concerns for PFOA apply to all members in this category.

a. *Human health hazard assessment.* EPA developed a National Primary Drinking Water Regulation for PFOA, which was finalized on April 26, 2024 (Ref. 33), and as part of the rulemaking, EPA published the “Final – Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA) and Related Salts” (Ref. 38). The Agency determined that PFOA is *Likely to be Carcinogenic to Humans* based on the 2005 *Guidelines for Carcinogen Risk Assessment* (Ref. 39) and developed a draft cancer slope factor (CSF) of 0.0293 (ng/kg bw-day)⁻¹ based on renal cell carcinomas in human males. The Agency also developed a draft chronic RfD of 3×10^{-8} mg/kg bw-day, based on the following co-critical effects: decreased anti-tetanus and anti-diphtheria antibody concentrations in children; decreased birth weight; and increased total serum cholesterol in adults. The Agency considers the RfDs to be applicable to both short-term and chronic risk assessment scenarios because two of the co-critical effects identified for PFOA are developmental effects that can potentially result from short-term PFOA exposure during a critical period of development. Therefore, short-term PFOA exposure during a critical period of development may lead to adverse health effects across life stages (Ref. 38).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFOA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(i) and (ii)(IV) for serious or irreversible chronic human health effects (including cancer and developmental effects).

13. *Perfluorooctanesulfonic acid (PFOS) (CASRN 1763-23-1), Salts, Sulfonyl Halides, and Anhydride Category.*

This category would include all associated salts and sulfonyl halides including: perfluorooctylsulfonyl fluoride (CASRN 307-35-7), perfluorooctanesulfonic anhydride (CASRN 423-92-7), potassium perfluorooctanesulfonate (CASRN 2795-39-3), sodium perfluorooctanesulfonate (CASRN 4021-47-0), ammonium perfluorooctanesulfonate (CASRN

29081-56-9) (currently TRI-listed as “1-Octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-, ammonium salt”), lithium perfluorooctanesulfonate (CASRN 29457-72-5) (currently TRI-listed as “lithium (perfluorooctane)sulfonate”), tetraethylammonium perfluorooctanesulfonate (CASRN 56773-42-3) (currently TRI-listed as “Ethanaminium, N,N,N-triethyl-, salt with 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-1-octanesulfonic acid (1:1)”), 1-octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-, compd. With 2,2'-iminobis[ethanol] (1:1) (CASRN 70225-14-8), magnesium bis(heptadecafluorooctanesulfonate) (CASRN 91036-71-4), and tetrabutylammonium perfluorooctanesulfonate (CASRN 111873-33-7). In January 2020, PFOS and five of its salts were automatically added to the TRI chemical list as individual chemicals pursuant to the NDAA section 7321(b)(1)(C) and (D). EPA is now proposing to list PFOS and its associated salts and sulfonyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the sulfonyl halides would be expected to be converted to PFOS in aqueous solutions. Therefore, the toxicity concerns for PFOS apply to all members in this category.

a. *Human health hazard assessment.* The Agency determined that PFOS is *Likely to be Carcinogenic to Humans* based on the 2005 *Guidelines for Carcinogen Risk Assessment* (Ref. 39) and developed a draft CSF of $39.5 \text{ (mg/kg bw-day)}^{-1}$ based on hepatocellular adenomas and carcinomas in female rats (Ref. 40). The Agency also developed a chronic RfD of 1.0×10^{-7} mg/kg bw-day, based on co-critical effects of decreased birthweight in infants and increased serum total cholesterol in adults. The Agency considers the RfDs to be applicable to both short-term and chronic risk assessment scenarios because one of the co-critical effects identified for PFOS is a developmental effect that can potentially result from short-term PFOS exposure during a critical period of development. Therefore, short-term PFOS exposure during a critical period of development may lead to adverse health effects across life stages (Ref. 40).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFOS, Salts, Sulfonyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(i) and (ii)(IV) for serious or irreversible chronic human health effects (including cancer and developmental effects).

14. *Perfluoropropanoic acid (PFPrA) (CASRN 422-64-0), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts, acyl halides, and the anhydride including: pentafluoropropanoic anhydride (CASRN 356-42-3), potassium perfluoropropanoate (CASRN 378-76-7), sodium perfluoropropanoate (CASRN 378-77-8), perfluoropropanoyl chloride (422-59-3), and perfluoropropanoyl fluoride (CASRN 422-61-7). In July 2023, EPA finalized a human health toxicity value for PFPrA (Ref. 41). Accordingly, PFPrA is automatically added to the TRI chemical list as of January 1, 2024, pursuant to the NDAA section 7321(c)(1)(A)(i). EPA is now proposing to list PFPrA and its associated salts and acyl halides and anhydride as a single TRI category, as the salts (including non-metal and alkali metal salts) would be expected to dissociate in aqueous solutions and the acyl halides and anhydride would be expected to be converted to PFPrA in aqueous solutions. Therefore, the toxicity concerns for PFPrA apply to all members in this category.

a. *Human health hazard assessment.* In a 28-day oral study in rats, increased relative liver weight was observed in males at ≥ 20 mg/kg-d, accompanied by hepatocyte lesions (primarily hypertrophy with some evidence of slight focal necrosis) and serum markers of hepatocellular/hepatobiliary injury (*i.e.*, increased ALT, ALP) at ≥ 80 mg/kg-d. Despite the lack of additional oral repeat-dose studies examining liver effects of PFPrA by which to evaluate similarity of results, this profile of PFPrA-induced liver effects is consistent with the liver toxicity observed in experimental rodents following oral exposure to perfluorobutanoic acid, a

closely related linear short-chain (4-carbon) perfluorocarboxylic acid (Ref. 41).

The PFPrA toxicity assessment derived a chronic RfD of 1×10^{-4} mg/kg-day based on liver effects (Ref. 41).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFPrA, Salts, Acyl halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible liver toxicity.

15. *Perfluoroundecanoic acid (PFUnA) (CASRN 2058-94-8), Salts, Acyl Halides, and Anhydride Category.*

This category would include all associated salts and acyl halides including: ammonium perfluoroundecanoate (CASRN 4234-23-5), potassium perfluoroundecanoate (CASRN 30377-53-8), sodium perfluoroundecanoate (CASRN 60871-96-7), calcium perfluoroundecanoate (CASRN 97163-17-2), and perfluoroundecanoic anhydride (CASRN 942199-03-3). EPA found evidence of both serious or irreversible human health effects and environmental effects due to PFUnA and its salts. EPA is proposing to list PFUnA and its associated salts and acyl halides as a single TRI category, as the salts would be expected to dissociate in aqueous solutions and the acyl halides would be expected to be converted to PFUnA in aqueous solutions. Therefore, the toxicity concerns for PFUnA apply to all members in this category.

a. *Human health hazard assessment.* In a combined repeat-dose oral toxicity study with a reproductive/developmental screening test, rats were exposed to PFUnA at daily doses of 0.1, 0.3, or 1.0 mg/kg-day; the study was conducted consistent with OECD 422 protocol. Following PFUnA exposure for 41-46 days, indicators of toxicity were observed in the liver, kidney, and spleen of adult male and female rats. Statistically significant increases in absolute and relative liver weights and histopathological evidence of altered tissue architecture (*e.g.*, hepatocellular hypertrophy) were observed in male (≥ 0.3 mg/kg-day) and female (1.0 mg/kg-day) rats. Serum

enzymes indicative of hepatocellular (*e.g.*, ALT) and biliary epithelial (*e.g.*, ALP) injury were also observed immediately after cessation of exposure but only in males at the high dose of 1.0 mg/kg-day. A statistically significant increase in a blood biomarker indicative of kidney injury (*i.e.*, BUN) was also observed in male and female rats at 1.0 mg/kg-day. The spleen was also adversely affected by oral PFUnA exposure, as statistically significant decreased absolute and relative organ weights were observed in male and female rats at 1.0 mg/kg-day. Developmental effects entailed statistically significant decreases in the body weight of male and female offspring, on PNDs 0 and 4, in litters of the high dose rats. Based on systemic organ toxicities in adults and body weight decrements in offspring, a study NOAEL of 0.3 mg/kg-day and LOAEL of 1.0 mg/kg-day were identified (Ref. 42).

The pattern of liver effects seen for PFUnA in the OECD 422 study are consistent with those seen for other, more well-characterized PFAS. Specifically, the RfDs for GenX and PFBA are based on the same liver foci (*e.g.*, increased organ weights; liver hypertrophy and associated pathological lesions), as described for PFUnA exposure by Takahashi *et al.* (2014) (Ref. 43).

b. *Conclusion.* EPA believes there is sufficient evidence to list the PFDoA, Salts, Acyl Halides, and Anhydride category on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV), for serious or irreversible liver, kidney, spleen, and developmental outcomes.

C. *What are the proposed individual chemicals?*

The following chemicals are being proposed as individually listed additions to the TRI list (*i.e.*, EPA did not identify known, associated salts for purposes of this proposed listing) and reason for inclusion:

- Broflanilide (CASRN 1207727-04-5), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health) and 313(d)(2)(C) (Effect on the Environment);
- 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl- (MeFBSA) (CASRN

68298-12-4), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl- (MeFBSE) (CASRN 34454-97-2), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- Cyclopentene, 1,3,3,4,4,5,5-heptafluoro- (HFCPE) (CASRN 1892-03-1), which is based on EPCRA 313(d)(2)(C) (Effect on the Environment);

- Ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt (CASRN 132843-44-8), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- 6:2 Fluorotelomer alcohol (6:2 FTOH) (CASRN 647-42-7), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- Fulvestrant (CASRN 129453-61-8), which is based on EPCRA 313(d)(2)(C) (Effect on the Environment);

- Hexaflumuron (CASRN 86479-06-3), which is based on EPCRA 313(d)(2)(C) (Effect on the Environment);

- Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)- (CASRN 132182-92-4), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- Perfluorotridecanoic acid (PFTrDA) (CASRN 72629-94-8), which is based on EPCRA 313(d)(2)(C) (Effect on the Environment);

- Perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt (EEA-NH₄) (CASRN 908020-52-0), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- 2-Propenoic acid, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl ester (MeFBSEA) (CASRN 67584-55-8). Which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- Pyrifluquinazon (CASRN 337458-27-2), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health);

- Tetraconazole (CASRN 112281-77-3), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health) and 313(d)(2)(C) (Effect on the Environment);
- Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tri-deca-fluorooctyl)silane (CASRN 51851-37-7), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health); and
- Trifluoro(trifluoromethyl) oxirane (HFPO) (CASRN 428-59-1), which is based on EPCRA 313(d)(2)(B) (Chronic Human Health).

The Agency has provided important endpoints in the following summary. For the full toxicological profile, please refer to the respective references.

1. *Broflanilide (CASRN 1207727-04-5)*.

EPA has previously reviewed broflanilide as part of the pesticide registration process under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

a. *Human health hazard assessment*. The target organs of broflanilide toxicity are the adrenal glands (rats, mice, and dogs) and ovaries (rats and mice). Adrenal effects include increased adrenal weights, increased incidence of adrenal cortex vacuolation and adrenal cortex hypertrophy in both sexes. Ovarian effects include increased incidence of ovarian interstitial gland vacuolation (Ref. 44).

For the Chronic Dietary Endpoint for the General Populations, A 2-generation reproductive toxicity study (MRID 50211379) was selected with a NOAEL of 3 mg/kg/day and a LOAEL of 8 mg/kg/day based on increased adrenal weights with corroborative histopathological findings (increased vacuolation and diffuse hypertrophy in the adrenal gland cortex) in both sexes and both generations. Although an apparent lower NOAEL (2 mg/kg/day) was identified for females in the chronic rat study, it was a reflection of dose selection. The selected POD of 3 mg/kg/day is still protective for the effects noted in the chronic rat study at the LOAEL of 7.1 mg/kg/day. An uncertainty factor of 100X (10X for interspecies extrapolation, 10X for

intraspecies variation, and 1X for FQPA SF) is applied. The chronic reference dose (cRfD) and chronic population adjusted dose (cPAD) is 0.03 mg/kg/day (Ref. 44).

The Cancer Assessment Review Committee (CARC) classified broflanilide as “Likely to be Carcinogenic to Humans” based on Leydig cell tumors and all ovarian tumors combined (granulosa cell benign and malignant, luteomas, thecomas and sex cord stromal tumors). The unit risk, Q_1^* (mg/kg/day)⁻¹, of broflanilide based upon male rat testicular Leydig cell tumor rates is 2.48×10^{-3} in human equivalents (Ref. 44).

b. *Ecological hazard assessment.* Although there were no effects seen at the highest dose tested in acute daphnia (*Daphnia magna*) and eastern oyster (*Crassostrea virginica*) tests, an acute study with mysid resulted in a LC₅₀ of 0.0215 µg a.i./L, with a steep dose response (35%, 95% and 100% mortality at 0.0202, 0.0284, and 0.0428 µg a.i./L respectively). Based on the mysid data, broflanilide is classified as very highly toxic to aquatic estuarine marine invertebrates. In chronic studies, the *Daphnia* NOAEC of 5.93 µg a.i./L was based upon 6-8% reductions in length, total offspring, birth rate, and time to first brood at 11.6 µg a.i./L. The mysid study did not establish a definitive NOAEC endpoint because at the lowest test concentration, 0.0018 µg a.i./L, there was 17% reduced survival for F1 and 22% reduced offspring per female (Ref. 45).

Studies with freshwater species *Chironomus dilutus* and *Hyaella azteca*, and the estuarine/marine species *Leptocheirus plumulosus* resulted in LC₅₀s of 9.99, 13.5, and 14 µg ai/kg dry sediment. In a 28-day spiked sediment test with *Leptocheirus plumulosus*, the NOAEC was determined to be 3.8 µg ai/kg dry sediment based on 12% reduced survival at the LOAEC. Broflanilide is highly toxic to honeybees (*Apis mellifera*) and bumble bees (*Bombus terrestris*) on both an acute contact and oral exposure basis. In an acute (single dose) contact and acute oral combined toxicity study with adult honeybees (*Apis mellifera*), the 48-hr contact LD₅₀ = 0.0088

$\mu\text{g a.i./bee}$ and acute oral $\text{LD}_{50} = 0.0149 \mu\text{g a.i./bee}$ (Ref. 45).

Broflanilide is persistent in terrestrial and aquatic environments. Broflanilide is stable to hydrolysis and soil photolysis and under anaerobic and aerobic conditions, and it persists in soil and water, with half-lives ranging from months to years (Ref. 45).

c. *Conclusion.* EPA believes there is sufficient evidence to list broflanilide pursuant to EPCRA section 313(d)(2)(B)(i) for cancer and (ii)(IV) for serious or irreversible chronic human health effects, as well as (d)(2)(C) for toxicity and persistence.

2. *1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-(MeFBSE) (CASRN 34454-97-2).*

a. *Human health hazard assessment.* 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-is also referred to by the synonym 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-1-butanesulfonamide (MeFBSE). Hepatic effects observed after subchronic oral exposure in adult rats included elevated absolute and relative liver weight and hepatocellular hypertrophy in both sexes, and hepatocyte necrosis in male rats, at 250 mg/kg-day. Compared with the control group, at 250 mg/kg-day, ALT levels of treated female rats were increased 1.6-fold, and in male rats were increased 1.3-fold. The dose-dependent increases in organ weight, incidence of histopathological alterations (*e.g.*, cellular hypertrophy and necrosis), and although not statistically significant, serum ALT, suggests liver injury following repeated exposure to MeFBSE. It should be noted that while these results suggest a dose-dependent progression of liver injury, the temporality of exposure duration is typically associated with increased incidence and/or severity of liver injury over time; however, longer duration studies to inform the influence of prolonged exposure on this liver injury profile are not available for MeFBSE (Ref. 46).

Renal changes were limited to increases in absolute and relative kidney weights in males

at 50 and 250 mg/kg-day. (There was only increased relative kidney weight in high-dose females.) No histopathology or clinical chemistry parameters indicative of kidney injury were reported. The changes observed in the kidney were primarily observed in male rats and were limited to organ weight information; as such, in the absence of confirmatory histopathological and/or clinical chemistry evidence of renal injury, it is unclear if the observations in kidney weight are adverse (Ref. 46).

Oral MeFBSE exposure also induced effects in a reproduction/developmental screening test in rats (performed in accordance with the OECD Test No: 422). MeFBSE caused significant decreases in livebirth and viability indices for pups, and the average number of pups/litter surviving to PND 5 were decreased at 250 mg/kg-day maternal dose (Ref. 46).

b. *Conclusion.* EPA believes there is sufficient evidence to list MeFBSE on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) based on serious or irreversible liver toxicity and developmental toxicity for this chemical.

3. *1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl- (MeFBSA) (CASRN 68298-12-4).*

a. *Human health hazard assessment.* 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl- is also referred to by the synonym N-(methyl)nonafluorobutanesulfonamide (MeFBSA). The single repeated-dose oral toxicity study with reproductive/developmental screen in rats showed decreased conception rate in female rats with corresponding decreases in fertility and gestation indices, increased postnatal loss and decreased viability index of pups, and decreases in pup weight and increases in the incidence of small pups during lactation. Given that there is a dose-response relationship with statistically significant changes compared to control rats for the viability index (Ref. 47), the NOAEL is n.d. and the LOAEL is 50 mg/kg-day for reproductive/developmental effects. However, there is uncertainty in the assignment of a

LOAEL of 50 mg/kg-day for post-natal loss and decreased viability since single litter losses contribute to the postnatal loss values. In summary, the available literature provides evidence that MeFBSA can be reasonably anticipated to cause serious or irreversible reproductive and developmental toxicity in humans (Ref. 47).

b. *Conclusion.* EPA believes there is sufficient evidence to list MeFBSA on the TRI pursuant to EPCRA section 313(d)(2)(B) for serious or irreversible reproductive and developmental toxicity.

4. *Cyclopentene, 1,3,3,4,4,5,5-heptafluoro (HFCPE; CASRN 1892-03-1).*

a. *Ecological hazard assessment.* The experimental data for HFCPE from aquatic toxicity studies includes acute toxicity endpoint values as low as of 0.19 mg/L in freshwater fish (96-hour LC₅₀ in *Oryzias latipes*), 0.26 mg/L in aquatic invertebrates (48-hour EC₅₀ for immobilization of *Daphnia magna*), and 0.9 mg/L in algae (72-hour EC₅₀ for decreased growth rate in *Pseudokirchneriella subcapitata*) (Ref. 48).

b. *Conclusion.* EPA believes there is sufficient evidence to list HFCPE on the TRI pursuant to EPCRA section 313(d)(2)(C)(i) for environmental toxicity.

5. *Ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt (CASRN 132843-44-8).*

a. *Human health hazard assessment.* The available toxicity data for ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt (CASRN 132843-44-8) (also referred to by the synonym lithium bis[(pentafluoroethyl)sulfonyl]azanide), obtained from an unpublished 28-day oral rat study, are limited but provide evidence that the liver is a sensitive target organ. The mid dose of 2 mg/kg-day was identified as a LOAEL based on hepatic effects, including increases in liver weight, serum chemistry changes associated with hepatotoxicity [e.g., alanine aminotransferase (ALT) and alkaline phosphatase (ALP)], increased incidence and

severity of hepatocellular hypertrophy in both sexes, and increased incidence of focal necrosis of hepatocytes in male rats (Ref. 49).

b. *Conclusion.* EPA believes there is sufficient evidence to list ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic human health effects (hepatotoxicity).

6. *6:2 Fluorotelomer alcohol (6:2 FTOH) (CASRN 647-42-7).*

a. *Human health hazard assessment.* Histopathological changes in the liver and kidney were reported in two subchronic rat and mouse feeding studies following exposure to 6:2 FTOH in the diet. The liver changes included elevated organ weight and/or hepatocellular hypertrophy (and in some studies, other hepatic lesions such as oval cell hyperplasia, cystic degeneration, and single cell necrosis). These alterations were observed in rats at ≥ 25 mg/kg-day and in mice at ≥ 5 mg/kg-day. In addition, the elevated clinical chemistry parameters indicative of hepatocellular injury are greater in females than males at the highest test concentrations (100 mg/kg/day and 250 mg/kg/day, for mice and rats, respectively) of 6:2 FTOH. In mice, hepatic clinical chemistry values, including serum ALT and AST were significantly increased at 100 mg/kg-day 6:2 FTOH in F0 males (2.5 to 5-fold) and F0 females (>5 -fold). Significant increments (compared with the control groups) were also observed in the 6:2 FTOH treated rat serum ALT (+57% increase in male rats at 125 mg/kg-day) and GGT (+188% increase in female rats and +57% increase in male rats at 125 mg/kg-day) levels. The additional target organ of 6:2 FTOH toxicity was the kidney in both rats and mice, with effects observed at ≥ 25 mg/kg bw-day in rats and 100 mg/kg bw-day in mice. At high doses of 6:2 FTOH, effects on the kidney were severe in rats, and identified as a cause of mortality in multiple studies (Ref. 50).

b. *Conclusion.* EPA believes there is sufficient evidence to list 6:2 FTOH on the TRI

pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic health effects (hepatotoxicity and nephrotoxicity).

7. *Fulvestrant (CASRN 129453-61-8).*

Fulvestrant is also referred to by the synonym (7 α ,17 β)-7-[9-[(4,4,5,5,5-pentafluoropentyl)sulfinyl]nonyl]estra-1,3,5(10)-triene-3,17-diol.

a. *Ecological hazard assessment.* As described in Unit II.B., EPA is exploring additional means for identifying chemicals as candidates for TRI listing. ECOTOX data describes environmental effects for fulvestrant (CASRN 129453-61-8) (Ref. 51). In *Daphnia magna* exposed to fulvestrant, mortality was observed at 0.129 mg/L (mean LC₅₀) after a 96-h exposure, and statistically significant reproductive effects of reduced brood size were observed at a lowest effect concentration of 0.001 mg/L in chronic tests (Ref. 52). Statistically significant abnormal development (defined as missing anatomical features, deformities, and incomplete gut development) was observed in sea urchin larvae, *Strongylocentrotus purpuratus*, exposed to fulvestrant both alone (EC₅₀ value of 0.000058 mg/L), as well as in co-incubation experiments with endocrine disrupting compounds (EDCs) resulting in increased developmental abnormalities by 10-20% (lowest effect concentration of 0.00003 mg/L) (Ref. 53). In mature male Atlantic croakers (*Micropogonias undulatus*), exposure to fulvestrant was observed to inhibit production of a predominant androgen, 11-ketotestosterone in *in vitro* cell cultures by functioning as an estrogen agonist when binding to the testicular estrogen membrane receptor at 0.055 mg/L (mean EC₅₀) (Ref. 54).

b. *Conclusion.* EPA believes there is sufficient evidence to list fulvestrant on the TRI pursuant to EPCRA section 313(d)(2)(C)(i) for environmental toxicity.

8. *Hexaflumuron (CASRN 86479-06-3).*

a. *Ecological hazard assessment.* Hexaflumuron is very highly toxic to aquatic

invertebrates, but not terrestrial invertebrates, birds, and mammals, on an acute exposure basis. In particular, hexaflumuron is very highly toxic to water flea (*Daphnia magna*), with a 48 hour LC₅₀ of 0.111 µg ai./L (Ref. 55).

On a chronic exposure basis, hexaflumuron resulted in reduced survival in birds (mallard duck and bobwhite quail) and reduced growth (pup body weights) in rats. In a 2-generation reproduction study with the rat (*Rattus norvegicus*), no adverse, treatment-related effects were observed on adult (parental) mortality, clinical signs, body weight, body weight gain, food consumption, hematology, organ weights, or gross or histological pathology throughout the study in either generation. However, the LOAEL for offspring toxicity was observed based on decreased pup body weights at 125 mg/kg bw/day dose level; the NOAEL was 25 mg/kg bw/day. In an avian reproduction toxicity study with mallard ducks (*Anas platyrhynchos*), the NOAEC was 29.4 mg ai./kg-diet (mean-measured) and the LOAEC was 96.5 mg ai./kg-diet (mean-measured) based on reduced survival (*i.e.*, reduced numbers of viable embryos and hatchling survival) and reduced growth (*i.e.*, hatchling body weights) (Ref. 55).

b. *Conclusion.* EPA believes there is sufficient evidence to list hexaflumuron on the TRI pursuant to EPCRA section 313(d)(2)(C)(i) for environmental toxicity.

9. *Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)- (CASRN 132182-92-4).*

a. *Human health hazard assessment.* The repeated exposure hazard studies for pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)- (CASRN 132182-92-4), referred to by the synonym 3-methoxyperfluoro(2-methylpentane), are limited to one 28-day oral rat study and a single generation reproductive/developmental study in rats via the inhalation route. Following oral exposure, the liver appears to be the most sensitive target organ. Gross enlargement and increased absolute and relative liver weights were statistically significantly

increased in male rats at ≥ 150 mg/kg-day, compared to control; increased liver weights in females were also observed but only at the high dose (1,000 mg/kg-day). Increased liver weight was accompanied by histopathological evidence of structural alteration (*e.g.*, centrilobular hepatocellular hypertrophy) in male rats at ≥ 150 mg/kg-day. Focal hepatocellular necrosis was also observed but only at the high dose (1,000 mg/kg-day). Based on findings of liver alterations in male rats, a LOAEL of 150 mg/kg-day and corresponding NOAEL of 25 mg/kg-day, are identified for oral 3-methoxyperfluoro(2-methylpentane) exposure (Ref. 56).

Increased liver weights were also noted at $\geq 72,250$ mg/m³ in F0 male rats of a single generation reproductive/developmental inhalation study; however, due to poor results reporting in the source ECHA study summary, incidence and/or magnitude of this effect was not discernable. Diffuse hepatocellular hypertrophy was also reported in the livers of these same male rats but again, incidence and magnitude of effect were not reported. Importantly, no evidence of statistically significant reproductive or developmental toxicity was reported in the F0 or F1 rats up to the highest inhalation concentration tested (281,700 mg/m³). Due to the lack of quantitative data provided in the source ECHA study summary, no LOAEC or NOAEC values were identified for the inhalation route of exposure (Ref. 56).

b. *Conclusion.* EPA believes there is sufficient evidence to list pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)- on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic health effects (hepatotoxicity).

10. *Perfluorotridecanoic acid (PFTrDA) (CASRN 72629-94-8).*

a. *Ecological hazard assessment.* The available aquatic toxicity data for perfluorotridecanoic acid (PFTrDA) (CASRN 72629-94-8) suggest high concern for hazard upon acute exposure of aquatic organisms to this chemical. Based on a 120-day fish study, a NOEC of 0.01 mg/L and LOEC of 0.1 mg/L (MATC = 0.03 mg/L) were identified in zebrafish for

significantly ($p < 0.05$) reduced survival into adulthood. In addition, based on a 48-hour EC_{50} of 8.2 mg/L for immobility in *D. magna*, PFTrDA can cause adverse aquatic effects. The MATC of 0.03 mg/L and EC_{50} of 8.2 mg/L were obtained based on nominal concentrations in a study that did not use solvent, and a MATC of 0.03 mg/L indicates a high concern for hazard to zebrafish upon chronic exposure to PFTrDA. It is likely that actual exposure levels were lower than nominal, and that the resulting MATC is lower as well (Ref. 57).

There is substantive evidence that PFTrDA has the potential to bioaccumulate in organisms. Laboratory and field-derived BCF and BAF values, respectively, suggest PFTrDA has a high potential to bioaccumulate in aquatic species (*e.g.*, BCF = 10,233 – 45,709 L/kg in zebrafish; root concentration factor (RCF) = 1,430 – 2,590 in aquatic plants; BAF = 19,953 – 31,623 L/kg in black-spotted frogs). Field studies also show that PFTrDA can biomagnify through the food chain (trophic magnification factor (TMF) = 3.54 – 4.78 at various sites in China and 0.9 – 14.9 at sites in France). However, there is no measured environmental half-life data for PFTrDA and the derived data via model predictions are unreliable for the chemical (Ref. 57).

b. *Conclusion.* The Agency believes there is sufficient data to list PFTrDA on the TRI pursuant to EPCRA section 313(d)(2)(C)(iii) for environmental toxicity and bioaccumulation.

11. *Perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt (EEA-NH₄) (CASRN 908020-52-0).*

a. *Human health hazard assessment.* Perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt is also referred to by the synonym perfluoro[(2-pentafluoroethoxy ethoxy)acetic acid] ammonium salt (EEA-NH₄).

An article by Rice *et al.* (Ref. 58) summarized the findings of two unpublished studies conducted by Asahi Glass. These studies were reported to follow OECD 407 and OECD 421

protocols designed to evaluate potential adverse health effects associated with repeated-dose (28-days) or reproduction and development in rats, respectively. After 28-days of oral EEA-NH₄ exposure, increased liver weights, hepatocellular hypertrophy, and increased kidney weight parameters were noted in male rats. For females, hepatocellular necrosis and renal tubule hyperplasia were observed. In the reproductive/developmental screening study, decreased body weight gains in parents and decreased body weight in pups, as well as decreased viability indices in pups were observed (Ref. 59).

In the 28-day (OECD 407) study, a LOAEL of 5 mg/kg/day was observed due to renal tubule basophilia in females. In males, increased liver and kidney weights were observed at 25 mg/kg/day. The study also observed other liver effects in male rodents at 100 mg/kg/day, including increased serum albumin to globulin ratio, increased alanine aminotransferase, decreased serum cholesterol, and hepatocellular hypertrophy. Decreased bilirubin and focal hepatocellular necrosis were noted in females at 100 mg/kg/day. Both sexes saw enlarged/squamous hyperplasia of the limiting ridge of the stomach at 100 mg/kg/day (Ref. 59).

In the OECD 421 study, the LOAEL was determined to be 30 mg/kg/day based on decreased body weight at PND 0 and 4 for both sexes of the F1 generation. At PND 6, decreased body weight was observed in male pups only at 90 mg/kg/day. Also, at 90 mg/kg/day, decreased birth index, increased total dead pups, and decreased total live pups/litter were observed. Adverse maternal reproductive effects included decreased body weight gain and feed consumption on Lactation Day (LD) 1–6 at 90 mg/kg/day (although mortality was also observed at 90 mg/kg/day) (Ref. 59).

b. *Conclusion.* EPA believes there is sufficient evidence to list EEA-NH₄ on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(I) for serious or irreversible reproductive dysfunctions and (IV) other chronic health effects.

12. *2-Propenoic acid, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl ester*

(*MeFBSEA*) (CASRN 67584-55-8).

a. *Human health hazard assessment.* Data on MeFBSEA (referred to by the synonym 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl 2-propenoate (MeFBSEA)) toxicity are limited to two unpublished oral toxicity studies in rats: a single 13-week oral repeat-dose study and a prenatal developmental toxicity study. Based on the available data showing organ weight, histopathological, and supporting serum chemistry changes, the liver and kidneys appear to be the most sensitive targets of toxicity. Elevated liver weights and histopathological changes were observed with increasing severity in male rats at ≥ 100 mg/kg-day and in female rats at ≥ 300 mg/kg-day. Measures of altered hepatic clinical chemistry were observed in both sexes at ≥ 300 mg/kg-day. At the high dose of 703 mg/kg-day, several animals died early, which the study authors attributed primarily to severe liver necrosis. Kidney weights were increased in both sexes at ≥ 100 mg/kg-day, and vacuolar degeneration and necrosis in the kidney were identified as contributing to early death in some rats. Effects of MeFBSEA in other tissues (urinary bladder, thyroid, adrenal gland) were mild and occurred primarily at high doses associated with overt clinical signs of toxicity and early mortality. In the developing fetus, decreased fetal body weights and increased skeletal variations were seen at doses ≥ 300 mg/kg-day in association with decreased maternal body weight (Ref. 60).

An additional potential target of toxicity is the urinary bladder in rats. Male rats dosed with 300 mg/kg-day demonstrated statistically significant reductions in mean body weights on Days 57 through 71 (-8 to -9%) and on Day 91 (-8%) (Ref. 60).

The liver effects (*e.g.*, hepatocellular hypertrophy, and gross enlargement of the liver) were observed in both male and female rats at 100 and 300 mg/kg/day, respectively (LOAEL=100 mg/kg/day). Statistically significant increases in serum alanine aminotransferase

(ALT) levels (+47%, 1.5-fold increment in comparison with the respective control value) in female and male rat (+73%, 1.6-fold increment in comparison with the respective control value), and statistically significant elevation of serum ALP level (+48%, 1.5-fold) in male rat were observed at 300 mg/kg/day. Additionally, coagulative necrosis in male rat liver and centrilobular necrosis in female rat liver were observed at 300 mg/kg/day. The microscopic histopathology findings correlated with concurrent and expected changes in serum clinical chemistry parameters and the severity of toxicity also reflected dose-related reductions in animal body weights over the dosing phase of this study at the highest test concentrations (1000/600 mg/kg/day) (Ref. 60).

Increased kidney weights were observed in both sexes of treated rat at ≥ 100 mg/kg-day. Vacuolar degeneration/necrosis, granular casts, increased severity of tubular basophilia were observed in the kidney of both sexes starting at 300 mg/kg/day of the test substance. Urinary bladder effects (hypertrophy/hyperplasia of the urothelium) of both sexes were also observed starting at 300 mg/kg/day (Ref. 60).

Under the treatment conditions, developmental effects following *in utero* exposure to MeFBSEA observed in the fetus included decreased fetal body weights and increased skeletal variations at doses ≥ 300 mg/kg-day (LOAEL) in association with decreased maternal body weight (Ref. 60).

b. *Conclusion.* EPA believes there is sufficient evidence to list MeFBSEA on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic health effects (hepatotoxicity, renal toxicity, and urinary bladder damage).

13. *Pyrifluquinazon (CASRN 337458-27-2).*

a. *Human health hazard assessment.* The Agency has provided important endpoints in the following summary. For the full toxicological profile, please refer to the respective reference (a 2018 EPA human health risk assessment for proposed uses of pyrifluquinazon (Ref. 61)). In a

carcinogenicity test in mice, the LOAEL was found to be 27.1/25.0 mg/kg/day [M/F] based on decreased mean body weight in males, increased incidences of tactile hair loss in males, endometrial hyperplasia of the uterine horn in females, follicular cell hypertrophy of the thyroid in males, and subcapsular cell hyperplasia of the adrenal in males. Using an uncertainty factor of 10X, the cPAD was calculated to be 0.06 mg/kg/day (Ref. 61).

In a two-generation developmental and reproductive toxicity study in rats, the developmental LOAEL was 10 mg/kg/day based on decreased anogenital distance (AGD) in males, increased incidences of skeletal variations (total), and increased incidences of supernumerary ribs. The offspring LOAEL was 10.2 mg/kg/day based on decreased body weight in F2 female pups (Ref. 61).

In a 28-day inhalation toxicity study in rats, the portal of entry LOAEL was 0.15 mg/L based on an increased incidence of terminal airway inflammation in males. The systemic LOAEL was 0.15 mg/L based on clinical signs including piloerection and splayed gait, decreased body-weight gains in both sexes, decreased platelet diameter widths in males, as well as increased incidence of centrilobular hepatocyte hypertrophy in both sexes (Ref. 61).

b. *Conclusion.* EPA believes there is sufficient evidence to list pyrifluquinazon on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(I) and (IV) for serious or irreversible reproductive dysfunctions and other chronic human health effects.

14. *Tetraconazole (CASRN 112281-77-3).*

a. *Human health hazard assessment.* The liver and kidney are the target organs of tetraconazole toxicity in oral toxicity studies in dogs and mice following subchronic and chronic durations: In a 90-day oral toxicity study in mice, single liver cell degeneration in males; and increased serum glutamic pyruvic transaminase (SGPT) and serum glutamic oxaloacetic transaminase (SGOT), decreased BUN levels, increased absolute and relative liver weights and

presence hepatocellular single cell necrosis in females were seen at the LOAEL of 16/20 mg/kg/day. In a chronic toxicity study in dogs, increases in liver weight and kidney weight, histopathological changes in the liver and kidney, and increases in alkaline phosphatase, γ -glutamyltransferase, alanine aminotransferase and ornithine carbamoyl transferase levels in both sexes, increased cholesterol in the male, decreased albumin in both sexes, proteinuria and decreased absolute terminal body weight in females were seen at the LOAEL of 12.97/14.5 (M/F) mg/kg/day. Inhalation exposure of rats to tetraconazole to resulted in portal-of-entry effects (squamous cell metaplasia of laryngeal mucosa and mononuclear cell infiltration) and systemic effects (follicular cell hypertrophy of thyroid). The inhalation no-observed-adverse-effect concentration (NOAEC) is established at 0.159 mg/L and lowest-observed-adverse-effect concentration (LOAEC) is 0.520 mg/L based on increased severity of the squamous cell metaplasia of laryngeal mucosa (minimal to slight), slight increase in severity of mononuclear cell infiltration, minimal epithelial erosion in the larynx, slight increase in the lung weights, and increased white blood cell counts. The systemic NOAEC is established at 0.0548 mg/L and LOAEC is 0.159 mg/L based on increased severity (minimal to slight) of thyroid follicular cell hypertrophy in males (Ref. 62).

In the developmental rat study, an increased incidence of supernumerary ribs (associated with 7th cervical vertebrae) was noted in the absence of maternal effects (developmental LOAEL = 100 mg/kg/day). In the two-generation reproduction toxicity study in rats, decreased litter and mean pup body weights were noted in offspring at the same dose that caused decreased body weights, dystocia, and mortality in adult females (offspring, reproductive, and parental/systemic LOAEL at the highest dose of 35.5/40.6 (M/F) mg/kg/day). Effects in parental animals that survived the duration of the study were consistent with other studies, such as decreased body weight, increased kidney weight, increased liver weight, and hepatocyte enlargement (Ref. 62).

The two-generation reproduction study in rats was selected for the chronic dietary endpoint for the general population. An uncertainty factor of 100 (10X for interspecies extrapolation, a 10X for intraspecies variability, and a 1X Food Quality PA Safety Act safety factor) was applied to the NOAEL of 6 mg/kg/day to generate the cPAD of 0.06 mg/kg/day. The LOAEL is 35.5 mg/kg/day based on decreased litter weight and mean pup weight in litters of all generations before weaning and decreased mean litter size and number of pups in the F1A generation. It is protective of the effects observed in the chronic studies in mice, rats, and dogs, as well as the fetal effect observed in the developmental study in rats (Ref. 62).

b. *Ecological hazard assessment.* Tetraconazole poses risk to terrestrial vertebrate and invertebrate taxa (primarily mortality, growth or reproduction effects from chronic exposure).

Chronic exposure of birds resulted in 7.48% and 15.9% reductions in 14-day old weight and survival, respectively. In a 2-generation reproduction study in rats, there was a 9% increase in mortality and a 2% increase in gestation times at the LOAEL of 5.9 mg a.i./kg-bw/day (females) (Ref. 63).

Available acute toxicity data for fish indicate that tetraconazole is moderately toxic to the freshwater Bluegill Sunfish (*Lepomis macrochirus*; LC50=3,850 µg a.i./L) and the estuarine/marine Sheepshead Minnow (*Cyprinodon variegatus*; LC50>3,400 µg a.i./L) on an acute exposure basis (Ref. 63).

In a chronic two-generation life cycle test (MRID 50485802) with the freshwater Zebra Fish (*Danio rerio*), the NOAEC was 80 µg a.i./L above which there was a statistically significant (p<0.05) shift in sex ratio (*i.e.*, 21.1% increase in the number of males and a 25.1% reduction females) compared to controls at the LOAEC of 207 µg a.i./L. A chronic early life stage toxicity test with the estuarine/marine *C. variegatus* resulted in a NOAEC of 120 µg a.i./L above which there were 3.2% and 10.8% reductions in body length and dry weight, respectively, at the

LOAEC of 240 µg ai/L (Ref. 63).

Tetraconazole is moderately toxic to the freshwater invertebrate waterflea (*Daphnia magna*; EC₅₀=2,360 µg a.i./L) and highly toxic to the estuarine/marine invertebrate mysid shrimp (*Americamysis bahia*; LC₅₀=440 µg a.i./L) on an acute exposure basis. A chronic toxicity study of the *D. magna* resulted in a NOAEC=190 µg a.i./L above which there was a 20.9% reduction in reproduction in comparison to the control at a LOAEC of 209 µg a.i./L. A chronic toxicity study with *A. bahia* resulted in a NOAEC of 87 µg a.i./L above which there was a 21% increase in the time to first brood, a 39% reduction in the number of young per female, and 10% decrease in male dry weight in comparison to the control at a LOAEC of 180 µg a.i./L (Ref. 63).

Tetraconazole is expected to be persistent in aquatic and soil environments and does not have a predominant route of dissipation. Tetraconazole is stable to hydrolysis and aerobic soil degradation. The aerobic aquatic half-lives ranged from 320 to 382 days. Tetraconazole field dissipation half-lives ranged from 91 to 800 days. Tetraconazole is stable to anaerobic aquatic metabolism with half-lives greater than the experimental period tested (t_{1/2}~ 8,123 days) (Ref. 63).

c. *Conclusion.* In conclusion, EPA believes there is sufficient evidence to list tetraconazole on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii) for serious or irreversible reproductive dysfunctions and other chronic health effects; as well as 313(d)(2)(C)(ii) for environmental toxicity and persistence.

15. *Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane (CAS 51851-37-7).*

a. *Human health hazard assessment.* Valid available toxicity data are limited to one repeat-dose oral study with a reproductive/developmental screen (OECD 422 guideline), a subchronic study for which EPA only has access to the industry summary(-ies) via ECHA database dossiers. The high dose tested was 128 mg/kg-day time weighted average (TWA)

(initially 150 mg/kg-day was tested and this was reduced to 125 mg/kg-day for the remainder of the study due to profound toxicity at 150 mg/kg-day in the first 1-2 weeks of exposure), the medium dose was 100 mg/kg-day, and the low dose was 50 mg/kg-day. The most sensitive toxicity target appears to be the peripheral nervous system. Clinical signs at ≥ 100 mg/kg-day included impaired neuromuscular function: ataxia, paresis, hypotonia, and reductions in reflexes, positional passivity, visual placing, grip strength, and sensitivity to pinching the tail. Histological evaluation showed progressive polyneuropathy in the peripheral nerves and associated myofiber atrophy/degeneration of skeletal muscles at ≥ 100 mg/kg-day (LOAEL). The authors of the study summary considered peripheral nerve polyneuropathy a contributing or primary cause of moribundity in 17/21 rats that were sacrificed moribund in the medium- and high-dose groups. In surviving animals from the high-dose group, neurological effects (clinical signs and polyneuropathy) persisted after a 14- to 16-day recovery period. No clinical signs of neurotoxicity or peripheral nerve damage were reported at 50 mg/kg-day (NOAEL). In summaries of acute duration studies, no apparent clinical signs of neurotoxicity were reported following oral or dermal exposure to 2,000 mg/kg (Ref. 64).

No direct effects were seen on reproductive viability, as based on gonadal cell observations, fertility rate, or pup health (up to sacrifice on PND 4) in any of the groups; however, the copulation rate was drastically reduced to 43% at the high dose of 128 mg/kg-day. This was due to the high mortality prior to mating, neuromuscular impairments in surviving rats that impacted mating success, and low survival of high-dose dams. Reproductive indices for the medium-dose group were similar to controls (therefore the NOAEL = 100 mg/kg-day). Due to the high mortality of the high-dose group mentioned previously, a LOAEL for reproductive/developmental toxicity could not be determined (Ref. 64).

In the lungs, increases in subacute perivascularitis and interstitial edema in the high dose

group (TWA of 128 mg/kg-day) were considered a contributing cause of moribundity in 5/21 rats. Hepatocellular hypertrophy and minimal-to-slight hepatocellular necrosis were observed in a few rats (as reported by the summary authors) that were sacrificed moribund in the medium and high dose groups (≥ 100 mg/kg-day). Diffuse hypertrophy of the zona fasciculata in the adrenal cortex was associated with moribundity in rats in the medium and high dose groups (≥ 100 mg/kg-day). Increases in thymic atrophy were also associated with moribundity in the high dose group (Ref. 64).

By the end of the 54-day study, half of the rats in the high-dose group had died. The 22 decedent rats from the medium- and high-dose groups were euthanized spanning Days 11 to 30. Exposed rats showed increased mortality in males, severe clinical signs of neurotoxicity (*e.g.*, ataxia, hypotonia, and paresis; occurred in both sexes but earlier in males than in females), decreased maternal body weight and body weight gain, and progressive polyneuropathy in both sexes (Ref. 64).

b. *Conclusion.* EPA believes there is sufficient evidence to list triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii)(IV) for serious or irreversible chronic health effects.

16. *Trifluoro(trifluoromethyl) oxirane (HFPO) (CASRN 428-59-1).*

a. *Human health hazard assessment.* The most reliable study for HFPO is a subchronic inhalation exposure study with reproductive screen in rats (OECD 422). Due to increased relative brain weight and corresponding brain lesions (neural necrosis and degeneration of neuronal fibers) in both sexes after exposure, HFPO is considered neurotoxic at $\geq 1,700$ mg/m³ (Ref. 65). An independent analysis of this chemical via a TSCA section 4 test order confirmed the same findings regarding the literature and toxic endpoints of HFPO: “In particular, available data from an OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental

Toxicity Screening Test in rats showed severe neurotoxicity, including vacuolization and/or necrosis of brain neuronal cells". The test order authors ranked this study as high confidence in the quality review of all health outcome endpoints (Ref. 66). Further, due to significant decreases in pup body weight in mid (1,700 mg/m³)- and high (TWA 3,660 mg/m³)-exposure groups in the same study, HFPO is expected to be a developmental toxicant. Note that a decrease in pup body weight was observed at the lowest concentration of 340 mg/m³ parental exposure, but the decrease was not statistically significant (Ref. 65). The test order corroborates findings of reproductive and developmental toxicity in the OECD 422 study.

b. *Conclusion.* EPA believes there is sufficient evidence to list HFPO on the TRI pursuant to EPCRA section 313(d)(2)(B)(ii) and (iv) for serious or irreversible nervous system and developmental toxicity endpoints.

IV. Chemicals on the TRI List are Being Reclassified as Chemical Categories

As explained in Unit II.B., EPA is proposing to reclassify certain individually listed chemicals as chemical categories. Specifically, EPA is proposing to remove the following individually listed chemicals from the TRI as they are included in chemical categories being proposed for listing (each is listed under the applicable category being proposed).

Hexafluoropropylene oxide dimer acid (HFPO-DA), Salts, and Acyl Halides Category:

- Hexafluoropropylene oxide dimer acid (HFPO-DA, GenX) (CASRN 13252-13-6);
- Hexafluoropropylene oxide dimer acid ammonium salt (CASRN 62037-80-3);
- Perfluorobutanesulfonic acid (PFBS), Salts, Sulfonyl Halides, and Anhydride Category;
- Perfluorobutanesulfonate (CASRN 45187-15-3);
- Perfluorobutanesulfonic acid (PFBS) (CASRN 375-73-5);
- Potassium perfluorobutane sulfonate (CASRN 29420-49-3);
- Perfluorobutanoic acid (PFBA), Salts, Acyl Halides, and Anhydride Category;

- Ammonium perfluorobutanoate (CASRN 10495-86-0);
- Perfluorobutanoate (CASRN 45048-62-2);
- Perfluorobutanoic acid (PFBA) (CASRN 375-22-4);
- Potassium heptafluorobutanoate (CASRN 2966-54-3);
- Sodium perfluorobutanoate (CASRN 2218-54-4);
- Perfluorodecanoic acid (PFDA), Salts, Acyl Halides, and Anhydride Category:
- Perfluorodecanoic acid (PFDA) (CASRN 335-76-2);
- Ammonium perfluorodecanoate (PFDA NH₄, CASRN 3108-42-7) (this chemical is not

currently listed in the CFR, but pursuant to NDAA section 7321(c) this chemical will be on the TRI list with an effective date of January 1, 2025, in response to a July 2024 IRIS publication on PFDA; accordingly, EPA plans to update the CFR in 2025 to include this chemical).

- Sodium perfluorodecanoate (PFDA-Na, CASRN 3830-45-3) (this chemical is not currently listed in the CFR, but pursuant to NDAA section 7321(c) this chemical will be on the TRI list with an effective date of January 1, 2025, in response to a July 2024 IRIS publication on PFDA; accordingly, EPA plans to update the CFR in 2025 to include this chemical);

Perfluorododecanoic acid (PFDoA), Salts, Acyl Halides, and Anhydride Category:

- Perfluorododecanoic acid (PFDoA) (CASRN 307-55-1);

Perfluorohexanesulfonic acid (PFHxS), Salts, and Sulfonyl Halides, and Anhydride Category:

- Perfluorohexanesulfonic acid (PFHxS) (CASRN 355-46-4);
- 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt

(CASRN 68259-08-5)

- 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, compd. With 2,2'-iminobis[ethanol] (1:1) (CASRN 70225-16-0)

- 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt (CASRN

3871-99-6)

- Perfluorononanoic acid (PFNA), Salts, Acyl Halides, and Anhydride Category:

- Perfluorononanoic acid (PFNA) (CASRN 375-95-1);

Perfluorooctanesulfonic acid (PFOS), Salts, Sulfonyl Halides, and Anhydride Category:

- Lithium (perfluorooctane)sulfonate (CASRN 29457-72-5);

- Potassium perfluorooctanesulfonate (CASRN 2795-39-3);

• 1-Octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluoro-, ammonium salt (CASRN 29081-56-9);

• Ethanaminium, N,N,N-triethyl-, salt with 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluoro-1-octanesulfonic acid (1:1) (CASRN 56773-42-3);

- Perfluorooctylsulfonyl fluoride (CASRN 307-35-7);

- Perfluorooctanesulfonic acid (PFOS) (CASRN 1763-23-1);

- Perfluorooctanoic acid (PFOA), Salts, Acyl Halides, and Anhydride Category:

- Perfluorooctanoic acid (PFOA) (CASRN 335-67-1);

- Silver(I) perfluorooctanoate (CASRN 335-93-3);

- Sodium perfluorooctanoate (CASRN 335-95-5);

- Potassium perfluorooctanoate (CASRN 2395-00-8);

- Ammonium perfluorooctanoate (CASRN 3825-26-1);

- Chromium(III) perfluorooctanoate (CAS RN 68141-02-6); and

- Octanoyl fluoride, pentafluoro- (CASRN 335-66-0).

EPA would only take final action to remove the individually listed chemicals if the chemical categories that encompass the chemicals are added to the TRI through a final agency action.

Category reporting would require the facility to submit only one form for a category,

which accounts for activities and quantities associated with all member chemicals. Facilities would first need to calculate the total weight of all chemicals that fall under a category for each threshold activity (*i.e.*, manufacture, process, and otherwise use), and compare the totals to the applicable threshold(s). If a facility exceeds one or more reporting thresholds (*i.e.*, for manufacture, process, and otherwise use) for a proposed PFAS category, it would be required to report the aggregated quantities of releases and other waste management activities of the chemicals in that chemical category.

For example, a facility that manufactures 75 pounds of perfluorobutanesulfonyl fluoride (CASRN 375-72-4) and 50 pounds of potassium perfluorobutane sulfonate (CASRN 29420-49-3) would exceed the 100-pound reporting threshold for the PFBS, Salts, Sulfonyl Halides, and Anhydride category. Therefore, the facility would need to submit one form for the PFBS category. On this TRI reporting form for the PFBS category, the facility would aggregate information for all members of the PFBS category.

Note that, as this proposed rule is written, it is possible for a PFAS category to be inclusive of a PFAS that has a CBI claim related to its identity, and in which case, it would need to be reported as part of that category. For reviewing toxicity data to support TRI listings, the Agency did not consider chemicals with CBI claims regarding their identities as individual chemical listing candidates or as chemicals for which toxicity information would be directly considered for listing purposes. However, it is conceivable that there may be a form of an acid (*e.g.*, a salt) that would fit into a category being proposed, as the proposed categories are open-ended and not limited to a discrete list of chemicals. Because reporting a TRI category only requires a facility to report the category name and not the specific individual members, it's possible a facility may meet reporting requirements for a PFAS category based on activities involving a PFAS with a CBI claim. However, the reporting form would only reveal the broader

category name and would not divulge the individual chemicals of that category involved. The EPA notes that it does not anticipate this scenario to be likely.

V. Reporting Threshold for PFAS EPA is Proposing to Add to the TRI

For PFAS added to the EPCRA section 313 toxic chemical list under the provisions of NDAA section 7321(b) and (c), Congress established a manufacture, processing, and otherwise use reporting threshold of 100 pounds for each of the listed PFAS. The 100-pound reporting threshold reflects a concern for small quantities of PFAS due to their toxicity and persistence in the environment. The PFAS proposed for addition in this action have similar properties as those added by the other sections of the NDAA. EPA finds that it is appropriate to maintain consistency for all chemicals added to TRI pursuant to the NDAA (*i.e.*, those PFAS previously added by NDAA section 7321(b) and (c)). Therefore, EPA is proposing to establish a 100-pound manufacture, processing, and otherwise use reporting threshold for the PFAS proposed for addition in this action. However, EPA is soliciting comment (see Unit VII.) on whether to implement a different reporting threshold (*i.e.*, whether a different threshold would equally or more capably obtain reporting on a substantial majority of total releases of these PFAS being proposed for addition to the TRI list). Similarly, should EPA implement a threshold other than 100 pounds for these PFAS, EPA is soliciting comment on whether to modify the reporting threshold for other TRI-listed PFAS accordingly.

Facilities are advised that some PFAS being proposed for listing in this action may fall under multiple TRI chemical categories. For example, silver heptafluorobutyrate (CASRN 3794-64-7) is being proposed as a member of the PFBA, Salts, Acyl Halides, and Anhydride category. Because of the silver constituent in the compound, it is also included in the silver compounds category. In cases where a TRI facility has a compound with constituents in two listed chemical categories, the facility must consider the total amount of the compound manufactured, processed,

or otherwise used that must be applied to the reporting threshold for each category separately. Using the example of silver heptafluorobutyrate, a facility which has manufactured that compound must apply the same compound to threshold determinations for each listed category separately and determine whether that amount manufactured meets the reporting threshold for PFBA compounds (100 lbs manufactured) and for silver compounds (25,000 lbs manufactured), independently. This is consistent with longstanding EPA guidance on reporting for compounds covered by multiple chemical categories.

VI. Designating PFAS Being Proposed for Addition as Chemicals of Special Concern

EPA is proposing to add all of the PFAS described in Unit III. to the list of chemicals of special concern at 40 CFR 372.28. EPA first created the list of chemicals of special concern to increase the utility of TRI data by ensuring that the data collected and shared through TRI are relevant and topical (64 FR 58666, 58668 October 29, 1999 (FRL-6389-11) (Ref. 67). EPA lowered the reporting thresholds for chemicals of special concern because even small quantities of releases of these chemicals can be of concern. The first chemicals that were added to the list of chemicals of special concern were those identified as persistent, bioaccumulative and toxic (PBT) which, except for the dioxin and dioxin-like compounds category, have reporting thresholds of either 10 or 100 pounds depending on their persistent and bioaccumulative properties (Ref. 67). Chemicals of special concern are also excluded from the *de minimis* exemption (for both TRI reporting and TRI supplier notification requirements), may not be reported on Form A (Alternate Threshold Certification Statement), and have limits on the use of range reporting.

The *de minimis* exemption allows facilities to disregard small concentrations of TRI chemicals not classified as chemicals of special concern in mixtures or other trade name products when making threshold determinations and release and other waste management calculations.

The *de minimis* exemption does not apply to the manufacture of a TRI chemical except if that chemical is manufactured as an impurity and remains in the product distributed in commerce, or if the chemical is imported below the applicable *de minimis* level. The *de minimis* exemption does not apply to a byproduct manufactured coincidentally as a result of manufacturing, processing, otherwise using, or any waste management activities. Further, facilities covered by TRI supplier notification requirements (40 CFR 372.45) may also use the *de minimis* exemption, except for chemicals of special concern.

The Form A provides facilities that otherwise meet TRI-reporting thresholds the option of certifying on a simplified reporting form provided that they do not exceed 500 pounds for the total annual reportable amount (defined subsequently in this document) for that chemical, and that their amounts manufactured, processed, or otherwise used do not exceed 1 million pounds. All chemicals of special concern (except certain instances of reporting lead in stainless steel, brass, or bronze alloys) are excluded from Form A eligibility. Form A does not include any information on releases or other waste management. Nor does it include source reduction information or any other chemical-specific information other than the identity of the chemical.

For certain data elements (Part II, Sections 5, 6.1, and 6.2 of Form R), for chemicals not classified as chemicals of special concern, the reportable quantity may be reported either as an estimate or by using the range codes that have been developed. Currently, TRI reporting provides three reporting ranges: 1–10 pounds, 11–499 pounds, and 500–999 pounds.

In the preamble to the 1999 rule establishing the *de minimis* exemption, EPA outlined the reasons for promulgating the *de minimis* exemption (*e.g.*, that facilities had limited access to information and that low concentrations would not contribute to the activity threshold) and determined that those rationales did not apply to chemicals of special concern. *Id.* At 58670. Among the reasons provided, EPA explained that even minimal releases of persistent

bioaccumulative chemicals may result in significant adverse effects that can reasonably be expected to significantly contribute to exceeding the proposed lower threshold. *Id.* EPA also determined that facilities reporting on chemicals of special concern could not avail themselves of Form A reporting because the information provided on Form As is “insufficient for conducting analyses” on chemicals of special concern and would be “virtually useless for communities interested in assessing risk from releases and other waste management” of such chemicals (*i.e.*, the Form A does not include estimated release and other waste management quantities). *Id.* Lastly, EPA determined that range reporting was not appropriate for chemicals of special concern because the use of ranges could misrepresent data accuracy for PBT chemicals because the low or the high-end range numbers may not really be that close to the estimated value. *Id.* For the full discussion, see “Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting” (Proposed rule (64 FR 688, January 5, 1999 (FRL-6032-3)) and Final rule (64 FR 58666, October 29, 1999 (FRL-6389-11) (Ref. 67)).

EPA recently finalized a rulemaking (88 FR 74360; (Ref. 68)) to categorize PFAS added to EPCRA section 313 by NDAA section 7321(b) and (c) as chemicals of special concern, listing such PFAS in 40 CFR 372.28. In that rulemaking, EPA highlighted that the NDAA set a 100-pound reporting threshold for PFAS added by NDAA section 7321(b) and (c), which indicates a concern for small quantities of such PFAS. Further, EPA explained that the availability of certain burden reduction tools (*i.e.*, *de minimis* levels, Form A, and range reporting) is not justified for chemicals where there is a concern for small quantities (88 FR 74360, 74363). This same rationale applies to the PFAS being proposed for addition in this rulemaking action.

Further, due to the strength of the carbon-fluorine bonds, EPA noted in the October 31, 2023, rulemaking that many PFAS can be very persistent in the environment (Ref. 3, 4, 69).

Persistence in the environment allows PFAS concentrations to build up over time; thus, even small releases can be of concern. As with PBT chemicals, permitting reporting facilities to continue to rely on the burden reduction tools (*de minimis* levels, Form A, and range reporting) would eliminate reporting on potentially significant quantities of the listed PFAS. As explained in more detail subsequently in this document, EPA's rationale for eliminating these burden reduction tools for PBT chemicals (64 FR 714-716) applies equally well to PFAS.

The *de minimis* exemption allows facilities to disregard concentrations of TRI listed chemicals below 1% (0.1% for carcinogens) in mixtures or other trade name products they import, process, or otherwise use in making threshold calculations and release and other waste management determinations. Since the *de minimis* level is based on relative concentration rather than a specific amount, the application of this exemption to PFAS listed under NDAA section 7321(d) could allow significant quantities of such PFAS to be excluded from TRI reporting by facilities. For example, if a facility imports, processes, or otherwise uses 100,000 pounds of a mixture or trade name product that contains 0.5% of a listed PFAS, then 500 pounds (or five times the reporting threshold) would be disregarded. This exemption thus is inconsistent with a concern for small quantities of PFAS. Many PFAS are used in products at levels below the established *de minimis* levels (Ref. 5, 70). If EPA were to allow entities to apply the *de minimis* exemption with respect to PFAS, facilities would be able to discount such uses when determining whether an applicable threshold has been met to trigger reporting.

Additionally, in EPA's recent rulemaking to categorize PFAS already on the TRI list as chemicals of special concern, EPA also eliminated the use of the *de minimis* exemption for supplier notification requirements for all chemicals of special concern (Ref. 2). EPA determined that allowing facilities covered by the TRI supplier notification requirements to continue the use of the *de minimis* exemption for supplier notifications for chemicals of special concern limited

TRI reporting facilities' knowledge of potentially reportable quantities of chemicals of special concern in their on-site activities. Many PFAS are used in products below the established *de minimis* levels (Ref. 5, 70) which results in downstream users of those products not knowing they are receiving a product that contains a TRI-reportable PFAS. EPA concluded that it is important and necessary to eliminate the supplier notification *de minimis* exemption for PFAS added to the TRI list pursuant to NDAA section 7321(b) and (c); otherwise, the Agency may fail to collect information on amounts of PFAS that significantly exceed the reporting threshold. The same logic extends to PFAS being proposed in this action pursuant to NDAA section 7321(d).

As described previously, the Form A provides certain covered facilities the option of submitting a substantially shorter form with a reduced reporting burden (Ref. 71). This means that if facilities that are required to report data on PFAS were able to file a Form A, those facilities would not be providing specific quantity data on up to 500 pounds of a listed PFAS (five times the reporting threshold). While the Form A does provide some general information on the quantities of the chemical that the facility manages as waste, this information may be insufficient for conducting analyses on PFAS and may be less meaningful for communities interested in assessing risk from releases of PFAS. The threshold category for amounts managed as waste does not include quantities released to the environment as a result of remedial actions or catastrophic events not associated with production processes (section 8.8 of Form R). This means that if facilities that are required to report data on PFAS were to qualify to file a Form A, they would not be providing specific quantity data on up to 500 pounds of a listed PFAS (five times the reporting threshold). Given that even small quantities of PFAS may result in elevated concentrations in the environment, EPA believes it would be inappropriate to allow a reporting option that would exclude information on some releases. For reporting year 2021, approximately 10% of the reporting forms submitted for the listed PFAS were Form As (*i.e.*, reporting for TRI

reflects 87 active reporting forms of which 78 were Form Rs and 9 were Form As).

For these reasons, as well as to align these proposed PFAS additions with the PFAS that the NDAA added directly to the TRI chemical list, eliminating the availability of the use of Form A for PFAS is consistent with a concern for understanding small quantities of PFAS.

For TRI-listed chemicals, other than chemicals of special concern, releases and off-site transfers for further waste management of less than 1,000 pounds can be reported using ranges or as a whole number. The reporting ranges are: 1–10 pounds; 11–499 pounds; and 500–999 pounds. For larger releases and offsite transfers for further waste management of the toxic chemical, the facility must report the whole number. Use of ranges could reduce data accuracy because the low- or the high-end range numbers may not be that close to the estimated value, even taking into account inherent data errors (*i.e.*, errors in measurements and developing estimates). For PFAS, it is important to have accurate data regarding the amount released even when the quantities are relatively small, since concern may be tied to even small quantities of a substance. This issue was apparent for PFAS for reporting year 2021 since much of the data reported was for less than 1,000 pounds.

EPA anticipates that the elimination of these burden reduction tools will increase the amount and quality of data collected for PFAS and is consistent with the concern for small quantities of PFAS (Ref. 2). Per the Ratio-Based Burden Methodology, the Form R unit burden per chemical is 35.70516 hours compared to the Form A unit burden per chemical of 22.0 hours. With a weighted average wage rate of \$79.23 and a first-time filer factor of 2.1, the Form R unit cost per chemical is \$5,941 and the Form A unit cost per chemical is \$3,661. To avoid understating per-firm impacts, EPA assumes each small entity will submit two Form Rs. Thus, small entities are expected to incur \$11,883 in costs for the first year compared to \$7,322 if they were allowed to submit two Form As instead.

VII. Clarifying the Framework for NDAA Section 7321(c) Additions

Additional PFAS are automatically added to the TRI list on an annual basis by NDAA section 7321(c). Specifically, PFAS that meet the criteria in NDAA section 7321(c) are deemed added to the TRI list on January 1 of the year after those criteria are met. The criteria that lead to listing pursuant to NDAA section 7321(c) are identified as follows:

- Final Toxicity Value. The date on which the Administrator finalizes a toxicity value for the PFAS or class of PFAS;
- Significant New Use Rule (SNUR). The date on which the Administrator makes a covered determination for the PFAS or class of PFAS;
- Addition to Existing SNUR. The date on which the PFAS or class of PFAS is added to a list of substances covered by a covered determination;
- Addition as an Active Chemical Substance. The date on which the PFAS or class of PFAS to which a covered determination applies is:
 - Added to the list published under TSCA section 8(b)(1) (*i.e.*, TSCA Inventory) and designated as an active chemical substance under TSCA section 8(b)(5)(A); or
 - Designated as an active chemical substance under TSCA section 8(b)(5)(B) on the TSCA Inventory.

For purposes of identifying PFAS that are automatically added to the TRI list following an event specified under NDAA section 7321(c), EPA considers any chemical to be a PFAS if it is identified by EPA as a PFAS in the event that triggers its listing pursuant to NDAA section 7321(c). This approach recognizes that different programs may have reason to use different definitions of PFAS and that definitions of PFAS may evolve. This approach is also consistent with the language used in NDAA section 7321(c), which deems chemicals included to TRI following an EPA action related to PFAS without limiting or defining what is meant by PFAS.

The first update rule identifying PFAS that met the NDAA section 7321(c) criteria during 2020 was published on June 3, 2021 (86 FR 29698) (FRL-10022-25)). NDAA section 7321(c) is self-implementing in that PFAS subject to the activities described previously are directly added to the TRI list with an effective date of January 1 of the year following the date on which the activity occurred. That is, no rulemaking is required to effectuate the addition, though EPA has promulgated associated rules to update 40 CFR 372.65 to include any such PFAS added to the TRI list.

To date, EPA's updates to 40 CFR 372.65 have only included a PFAS if the CASRN associated with the PFAS was specifically listed in a triggering event, and if EPA, as part of the triggering event, explicitly identified that substance as a PFAS. For instance, in December 2022, EPA published an IRIS toxicity assessment for perfluorobutanoic acid (PFBA, CASRN 375-22-4) and related salts (Ref. 25). The assessment stated that the toxicity value derived for PFBA also applies to PFBA's salts, providing the following as examples in the document: sodium perfluorobutanoate (CASRN 2218-54-4), potassium heptafluorobutanoate (CASRN 2966-54-3), ammonium perfluorobutanoate (CASRN 10495-86-0), and perfluorobutanoate (CASRN 45048-62-2). Thus, pursuant to NDAA section 7321(c), EPA promulgated a final rule in 2023 (88 FR 41035; June 23, 2023) to update the list of TRI chemicals at 40 CFR 372.65 to include each of the aforementioned PFAS individually.

The approach described above to list perfluorobutanoic acid and its salts is in tension with the approach proposed in this notice to list a PFAS acid along with its salts and/or acyl/sulfonyl halides and anhydride as a category. Applying the approach described in this proposal to list certain PFAS as TRI chemical categories (*i.e.*, a category comprised of the acid, associated salts, and acyl/sulfonyl halides) to PFAS automatically added to TRI by NDAA section 7321(c) would result in consistent TRI listings so that all acids and associated salts and

acyl/sulfonyl halides would be TRI-listed as categories. If PFAS automatically added to TRI due to the triggering actions were not listed similarly at the time of their addition to the TRI list as the PFAS chemical categories being proposed in this rulemaking, inconsistencies would arise with how NDAA-added PFAS are reported. This would complicate the reporting scheme and introduce inconsistencies in the reported data, thereby burdening EPA, reporting entities, and other TRI data users due to this lack of consistency. Further adding to the TRI list in the CFR only those CASRNs identified as examples in an action that triggers the TRI listing could potentially leave some PFAS added to the TRI by NDAA section 7321(c) off the TRI list in the CFR creating confusion for the regulated community. For example, where a triggering action provides examples of the CASRNs covered, but does not list all of the CASRNs covered individually, EPA's update to the CFR could leave off related PFAS that were covered by the triggering event but were not listed as examples of covered substances (*e.g.*, where a document that finalizes a toxicity value identifies specific chemical names/CASRNs as well as states that the toxicity value applies to salts of the given chemical). Additionally, NDAA section 7321(c) provides for the addition of "a perfluoroalkyl or polyfluoroalkyl substance" as well as a "class of perfluoroalkyl or polyfluoroalkyl substances." Given the TRI context for NDAA section 7321(c), interpreting "class of perfluoroalkyl or polyfluoroalkyl substances" to mean that a TRI chemical category is created for PFAS and associated chemicals (*e.g.*, salts and/or acyl/sulfonyl halides) when a finalized toxicity value applies aligns with the statutory language.

Thus, where the triggering action is applicable to both the acid and associated salts and/or acyl/sulfonyl halides, EPA is proposing regulatory text that would designate each PFAS added in the future pursuant to NDAA section 7321(c) as a chemical category of the acid and associated salts and acyl/sulfonyl halides. Specifically, if EPA includes language as part of the NDAA section 7321(c) triggering action (*e.g.*, finalizing a toxicity value, or adding to an existing

SNUR) that the action is applicable to related chemicals (*e.g.*, by naming one or more associated salt(s), acyl/sulfonyl halide(s), or similar associated compound), then EPA will interpret the action to be a triggering event under NDAA section 7321(c) for all identified types of PFAS (*i.e.*, the acid, salts, and acyl/sulfonyl halides) and those PFAS will be automatically added to the TRI list as a chemical category. For example, if EPA publishes a final toxicity value for a given PFAS and its salts (by either specifying the CASRNs for at least some of the associated salts or providing a general statement that the toxicity value applies to salts associated with the chemical), the resultant addition to the TRI list will be a chemical category comprising of that PFAS (acid) as specified in the published final toxicity value and its associated salts and acyl/sulfonyl halides. EPA requests comment on this approach.

Further, EPA notes that certain final toxicity values may omit related salts, acyl/sulfonyl halides, and anhydrides that have at least the same toxicity as the acid, if not more, due to the additional contributions to the overall chemical's toxicity from substituents unrelated to the acid. Generally, provided the final toxicity value indicates that it applies to salts and other forms of the chemical then all such compounds would be included in the resulting TRI chemical category. Where the final toxicity value only applies to certain chemicals but omits some due to additional contributions of toxicity, the resulting TRI chemical category will also include such chemicals. To use the same example of the 2022 IRIS assessment for PFBA and its related salts: the assessment stated it would not necessarily apply to non-alkali metal salts of PFBA, such as silver heptafluorobutyrate (CASRN 3794-64-7) due to the metal's PFBA-independent contribution to toxicity. For PFBA, the finalized toxicological review document determined that "due to the possibility of PFBA-independent contributions of toxicity", the final toxicity value excluded silver heptafluorobutyrate. Thus, because the toxicity of silver heptafluorobutyrate is at least comparable to that of the final toxicity value for PFBA, silver heptafluorobutyrate would be

included in the resulting TRI PFAS category for PFBA.

Put another way, where a PFAS final toxicity value omits specific substances, the explicitly omitted PFAS generally would not be deemed to be part of the category added to the TRI by the triggering event unless the reason for the omission is due to the identified substances as having additional toxicological concerns. Where the final toxicity value indicates that it only applies to a set of specifically identified chemicals, and not to a broader set of similar chemicals (*e.g.*, salts) then the chemical category deemed added to the TRI by NDAA section 7321(c) generally would include only those specifically identified PFAS.

EPA requests comment on this approach and on an alternate approach under which salts and halides omitted from the category would be excluded regardless of whether the finalized publication providing the toxicity value indicates that the toxicity concern would similarly apply to salts and/or halides. If this latter approach were adopted, EPA would plan to subsequently add the salts and halides to TRI through a separate rulemaking.

Additionally, NDAA section 7321(c) effectuates TRI listings based on certain EPA activities that may include the identities (name and/or CASRN) of ions (*i.e.*, cations/anions). Accordingly, such (an)ions have been added to the TRI (*i.e.*, perfluorobutanoate (CASRN 45048-62-2)). However, EPA has previously indicated that an ion does not meet the definition of a chemical for purposes of listing on the EPCRA section 313 list (59 FR 61432, 61460 (FRL-4922-2)) (Ref. 11). EPA considers the addition of an ion, or anion, of a chemical as being, in effect, an addition of a category of such compounds that dissociate in water (*e.g.*, salts). To align the listing of such (an)ions with longstanding TRI policy and to ensure consistent reporting of NDAA-added PFAS, EPA proposes to list any (an)ion identified by a NDAA section 7321(c) action as part of a category for the associated acid, as is being proposed for other PFAS in this rulemaking.

In NDAA section 7321(c)(1)(A)(i), Congress provided that substances are added to TRI as of January 1 of the year after the Administrator “finalizes a toxicity value for the perfluoroalkyl or polyfluoroalkyl substance or class of perfluoroalkyl or polyfluoroalkyl substances.” Congress did not, however, define the term “toxicity value.” Nor did Congress indicate what EPA activities or publications might constitute finalized toxicity values for purposes of this provision. EPA has not previously articulated an interpretation of the term “toxicity value” as it relates to NDAA section 7321(c)(1)(A)(i). In the absence of a statutory definition for “toxicity value”, EPA assumes Congress intended to use the term as it is most commonly used in the scientific community. For example, the California Department of Toxic Substances Control defines the “noncancer toxicity value” as “the amount of a chemical or contaminant that a person can ingest or breathe every day for a lifetime without any expected adverse health effects.” (Ref. 72). EPA has previously described toxicity values and examples of toxicity values: “Toxicity values (including reference doses [RfD], reference concentrations [RfC], cancer slope factors, and inhalation unit risks) needed for use in human health risk assessment are generally derived by reviewing available dose-response data in animals or humans, selecting a point of departure in the data that is judged most suitable, and adjusting for associated uncertainties” (Ref. 73). EPA believes it is most consistent with the plain scientific meaning of “toxicity value” to interpret the term in this context as referring to the analysis and establishment of a value at which adverse effects of a substance may occur or a value at which adverse effects of a substance are not anticipated to occur. EPA produces various types of toxicity assessments that provide toxicity values. These toxicity assessments typically include hazard identification, dose-response assessment, and—as examples—derive “toxicity values” for adverse noncancer effects (called oral reference doses [RfDs], inhalation reference concentrations [RfCs]) and/or cancer effects (called cancer slope factors [CSFs], inhalation unit

risk [IURs]) after chronic and/or subchronic exposure and determine cancer descriptors when cancer data are available. Listed below are EPA events considered to provide “toxicity values.”

To assist stakeholders in understanding how EPA interprets NDAA section 7321(c), EPA is proposing to provide a list of EPA events which the Agency is interpreting as “finaliz[ing] a toxicity value for the perfluoroalkyl or polyfluoroalkyl substance or class of perfluoroalkyl or polyfluoroalkyl substances” as used in NDAA section 7321(c)(1)(A)(1). These EPA events analyze and establish a value at which adverse effects of a substance may occur or a value at which adverse effects of a substance are not anticipated to occur. These values can be finalized by the Agency through the following types of events which, would trigger addition of the PFAS or class of PFAS to TRI under NDAA section 7321(c):

- EPA’s IRIS Program develops human health assessments that identify and characterize health effects information on environmental chemicals to which the public may be exposed, including derivation of toxicity values. The publication of a final IRIS assessment on the EPA website that provides a toxicity value for one or more PFAS would constitute a triggering event for those PFAS under NDAA 7321(c)(1)(A)(1). Each IRIS assessment can cover a chemical, a group of related chemicals, or a complex mixture. IRIS assessments are an important source of toxicity information used by EPA, state and local health agencies, other federal agencies, and international health organizations. IRIS assessments provide various types of toxicity values for health effects resulting from chronic exposure to chemicals, including reference concentrations (RfC) (an estimate of a continuous inhalation exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime), reference dose (RfD) (an estimate of a daily oral exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime), and cancer descriptions (including how likely the substance is to be carcinogenic as well as estimates of the increased cancer risk from

oral and inhalation exposures). A final IRIS assessment, thus, provides toxicity values for a chemical. Publication of a final IRIS assessment on a PFAS would cause that PFAS, if not already on the TRI list, to be added to the TRI list pursuant to NDAA 7321(c)(1)(A)(1).

- EPA's Provisional Peer-Reviewed Toxicity Values (PPRTVs) Program develops assessments which provide toxicity information and toxicity values for the Superfund Program (which is responsible for cleaning up some of the nation's most contaminated land and responding to environmental emergencies, oil spills and natural disasters). The publication of a final assessment on the EPA website that provides a toxicity value for one or more PFAS would constitute a triggering event for those PFAS. The PPRTV Program supports the Agency's mission to protect human health and the environment by identifying and characterizing the health hazards of—and providing an important source of toxicity information and toxicity values for—chemicals of concern to the Superfund Program. PPRTV assessments are developed in response to requests from EPA's Superfund Program to the Superfund Health Risk Technical Support Center (STSC) within EPA's Office of Research and Development's (ORD's) Center for Public Health and Environmental Assessment (CPHEA). PPRTVs are derived after a review of the relevant scientific literature and using Agency methodologies, practices, and guidance for the development of toxicity values (*e.g.*, oral RfDs, inhalation RfCs, provisional oral slope factors (p-OSF), and provisional inhalation unit risks (p-IUR)). A final PPRTV, thus, provides toxicity values for a chemical. Publication of a final PPRTV on a PFAS would cause that PFAS, if not already on the TRI list, to be added to the TRI list pursuant to NDAA 7321(c)(1)(A)(1).

- EPA develops EPA Transcriptomic Assessment Products (ETAP) for chemicals lacking traditional toxicity testing data. Using transcriptomics, which measures gene activity, ETAP determines the daily dose of a chemical where there is likely no appreciable human health risk. More specifically, an ETAP provides toxicity values by correlating gene activity from short-term

transcriptomic studies with toxicological responses from chronic toxicity tests. The measured gene activity is used to identify doses that cause toxicity. EPA follows a standard methodology for performing the studies and developing the assessments. ETAP reports provide a transcriptomic reference value (TRV), an estimate of a daily oral dose to the human population that is likely to be without appreciable risk of adverse non-cancer health effects over a lifetime. A final ETAP report, thus, provides toxicity values for a chemical. Publication of a final ETAP report on a PFAS would cause that PFAS, if not already on the TRI list, to be added to the TRI list pursuant to NDAA 7321(c)(1)(A)(1).

- EPA prepares toxicity values to support pesticide registrations or review of registrations pursuant to FIFRA section 3. Before manufacturers can sell pesticides in the U.S., EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards for registration. The registration process includes the submission and evaluation of data pertaining to the identity, composition, toxicity, exposure, and environmental fate of each pesticide. Pursuant to FIFRA, EPA assesses a variety of potential human health and environmental effects associated with use of the pesticide product for which registration has been requested, or for which registration review is ongoing. This includes developing risk assessments that evaluate the potential for harm to humans, wildlife, fish, and plants, including endangered species and non-target organisms, and which may derive toxicity values such as a population-adjusted dose (PAD) or RfD. Pesticide registration reviews must address several factors before establishing a tolerance, including but not limited to: cumulative effects from exposure to pesticides that share a mechanism of toxicity; whether the pesticide produces human health effects similar to effects caused by naturally-occurring estrogen or other endocrine-disruption effects; and whether infants, children, or other sensitive subpopulations are more susceptible due to exposure to the pesticide. Publication of a final risk assessment prepared in support of a pesticide registration or

registration review decision for a PFAS would cause that PFAS if not already on the TRI list to be added to the TRI list pursuant to NDAA 7321(c)(1)(A)(1).

- EPA derives toxicity values pursuant to TSCA section 6, which requires EPA to develop risk evaluations on chemicals designated as high-priority substances. Risk evaluations include the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations. Publication of a TSCA section 6 final risk evaluation that provides a final toxicity value on a PFAS would constitute a triggering event for the PFAS covered by that toxicity value. TSCA requires that risk evaluations conducted by EPA “integrate and assess available information on hazards.” 15 USC 2605(b)(4)(F)(i). Accordingly, in a risk evaluation, EPA identifies the adverse health or environmental effects caused by exposure to the subject chemical. Hazards may include, but are not limited to, toxicity with respect to cancer, mutation, reproductive, developmental, respiratory, immune, cardiovascular impacts, and neurological impairments, and a point of departure (POD) or cancer risk is calculated. A final risk evaluation, thus, provides toxicity values for a chemical. Publication of a final risk evaluation on a PFAS would cause that PFAS if not already on the TRI list to be added to the TRI list pursuant to NDAA 7321(c)(1)(A)(1).

- EPA derives toxicity values to support regulatory and non-regulatory activities under the Safe Drinking Water Act and Clean Water Act. The EPA’s Water Program develops human health assessments called Toxicity Assessments or Health Effects Support Documents (HESDs), that identify and characterize health effects information on chemicals that are known or likely to be found in water, including derivation of toxicity values and determination of cancer descriptors when cancer information is available. The publication of a final assessment that provides a toxicity value for a PFAS would constitute a triggering event. EPA develops human health assessments to support rules or drinking water and other health advisories. These assessments are

called Toxicity Assessments or Health Effects Support Documents (HESDs) and they identify and characterize health effects information on chemicals that are known or likely to be found in water. They also include derivations of toxicity values and determinations of cancer descriptors when cancer information is available. These documents provide the underlying RfD or, if applicable, the cancer risk values for drinking water contaminants that support the associated Health Advisory. A final HESD, thus, provides a toxicity value for a chemical. Publication of a final HESD on a PFAS would cause that PFAS if not already on the TRI list to be added to the TRI list pursuant to NDAA 7321(c)(1)(A)(1).

- Other toxicity values that EPA's offices finalize. For example, in addition to the IRIS program and PPRTV assessments noted previously, ORD publishes other toxicity assessments that include toxicity values. Publication of a final toxicity assessment that provides a toxicity value for one or more PFAS would constitute a triggering action for those PFAS.

Whenever one of the triggering actions identified here is taken for a PFAS that is not on the TRI list, then, as provided by NDAA section 7321(c), such a PFAS would be added to the TRI list with an effective date of January 1 of the following calendar year.

EPA is proposing to explain what Agency events constitute finalization of a toxicity value for a PFAS or class of PFAS to ensure consistent implementation of the statutory provision (*i.e.*, NDAA section 7321(c)). The Agency recognizes that Congress did not limit the term "toxicity value" to values finalized by any particular program such as EPA's IRIS program or to values finalized by any specific EPA office, but instead used broad language referring to "a toxicity value for the perfluoroalkyl or polyfluoroalkyl substance or class of perfluoroalkyl or polyfluoroalkyl substances" finalized by the Administrator. This statutory language covers actions "by the Administrator" to finalize toxicity values. By referencing actions taken "by the Administrator" instead of specifying actions taken by a particular EPA office, division or

program, Congress provided that values finalized by any Agency office, division or program may trigger TRI listing. For purposes of TRI listing, it does not matter which Agency program finalizes the toxicity value. Moreover, recognizing that NDAA section 7321(c) covers toxicity values finalized by multiple types of Agency actions and programs is consistent with the purpose of EPCRA section 313 as described by Congress in paragraph (h) (*i.e.*, to provide information to the public and governmental entities; to assist in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes). Ensuring that TRI data on PFAS are available may be helpful to inform the public and also, may assist EPA programs to assess risk by using the TRI exposure information. Further, as the NDAA did not define “finalize a toxicity value” nor limit the scope to only certain EPA programs or authorities involving toxicity values, the Agency concludes it is reasonable to interpret this provision as applying to multiple Agency actions, as defined previously.

Further, the NDAA did not expand on the meaning of “finalize”. In the absence of a congressional definition, EPA assumes Congress intended to use the plain meaning of the term “finalize.” Merriam-Webster's online dictionary's (<https://www.merriam-webster.com>) first definition of “finalize” is “to put in final or finished form” (see also Webster's Third New International Dictionary of the English Language 851 (1993)) but there is no universally recognized understanding of what that means in this context. In the context of the section 7321 of the NDAA, the Agency proposes to conclude this means to produce a toxicity value for a chemical following established Agency regulations, guidance, protocol, or procedure(s). The process for finalizing a toxicity value might differ slightly depending on the unique needs or evaluations performed by individual EPA offices or programs; however, as previously explained, each triggering event described in this proposal results in the analysis and establishment of a value at which adverse effects of a substance may occur or a value at which adverse effects of a

substance are not anticipated to occur. EPA has determined that its interpretation is consistent with historical application of the word “final” or “finalizes”, as well as the intent of the Sec. 7321 of the NDAA to “improve transparency by requiring emitters to report to the EPA the release of any of one of hundreds of PFAS compounds into the environment”. (165 Cong. Rec. S4531-01 (June 26, 2019) (statement of Sen. Shelley Capito)).

EPA proposes to conclude that when EPA publishes or issues one of the document types identified above, including when it takes final action to update or revise such a document, and that document includes a toxicity value for a PFAS, the Agency is at that time ‘finalizing a toxicity value’ as that term is used in the 2020 NDAA. This approach recognizes that each of the document types described above, when published or issued, include EPA's final assessment of hazard information regarding a particular chemical substance.

This reading is consistent with the approach taken by Congress in paragraph (b) of section 7321 of the NDAA. Paragraph (b) identifies specific PFAS that are added to TRI beginning January 1 of the calendar year following enactment of the 2020 NDAA. The chemical substances that Congress identified for immediate inclusion on TRI included chemicals for which EPA was, at the time of the NDAA’s passage, undertaking toxicity assessments to derive related toxicity values beyond the IRIS program. For example, EPA published for public comment draft drinking water Human Health Toxicity Values for GenX chemicals in 2018 (Ref. 74) and released a final Health Effects Support Document for PFOS in 2016 (Ref. 75). At the time of the NDAA’s enactment, Congress immediately added PFAS (GenX and PFOS) for which only non-IRIS toxicity values were either published or under review. Further, the IRIS assessments and the documents published or issued by other EPA programs identified above as events which would trigger addition of the PFAS or class of PFAS to TRI under NDAA section 7321(c), due to their finalizing toxicity values for PFAS, all contain rigorous evaluations of data

to support finalization of a toxicity value. The scientific rigor of these documents is consistent with the rigor of scientific literature used for chemical listings pursuant to EPCRA section 313(d)(2). In other words, each of the above listed EPA triggering events aligns with publications that the Agency would use to support a TRI listing. Congress, in providing paragraph 7321(c)(1)(A)(i) of the NDAA, created a mechanism that would alleviate EPA from conducting an EPCRA section 313(d)(2) rulemaking to list chemicals for which the Agency had developed support for a TRI listing. And, thus, this provision fast tracks the addition of such chemicals to assist in the collection of TRI data to further the statute's purposes.

For purposes of which chemicals constitute "PFAS" pursuant to triggering events provided in NDAA section 7321(c), EPA considers any chemical to be a PFAS if it is determined to be a PFAS by the applicable EPA action. EPA anticipates that most EPA activities that trigger additions of PFAS to TRI will determine the chemical to be PFAS as part of the action, thereby obviating the need to apply a specific definition to determine whether the chemical is a PFAS for purposes of NDAA section 7321(c). As explained in Unit II.A., this approach of treating chemicals as PFAS if they are determined to be PFAS by the applicable triggering EPA event supports the scope of TRI, helping to ensure that data on PFAS is available to help support informed decision-making by companies, government agencies, non-governmental organizations, and the public.

For example, 1,1,1-Trifluoro-N-[(trifluoromethyl)sulfonyl] methanesulfonamide (TFSI) is not a PFAS per the definition being used for purposes of identifying PFAS candidates for this rulemaking. However, EPA published a final human health toxicity value for TFSI in July 2023 that also applies to the related salt (*e.g.*, lithium bis[(trifluoromethyl)sulfonyl]azanide (HQ-115) (CASRN 90076-65-6). Accordingly, this chemical, due to it being labeled a PFAS by the published document, is on the TRI list with an effective date of January 1, 2024. Pursuant to the

proposed CFR text for implementing the automatic addition of PFAS process provided by NDAA section 7321(c), if finalized, TFSI would be added to the TRI list as a chemical category that includes TFSI and any associated salts (note that acyl/sulfonyl halides and anhydrides would not be relevant to this category).

VIII. Request for Comment

In this document, EPA is providing an opportunity for public comment on the actions proposed herein and the rationale for those proposed actions. EPA is also specifically requesting public comment on the following topics:

1. EPA seeks comment on its category approach for listing and grouping PFAS for TRI reporting purposes (*i.e.*, Acid, Associated Salts, Acyl/Sulfonyl Halides, and Anhydride). Specifically, EPA solicits comment on the Agency's proposed chemical categories and whether they should include any or all such compounds related to the acid (that is, salts, acyl/sulfonyl halides, and anhydrides), or to keep such additional, related listings separate as individual listings. For instance, the Agency is requesting comment on the examples the Agency is proposing to list in this rule as additions based on their inclusion in their respective categories: perfluorobutanoyl fluoride (CASRN 335-42-2) based on perfluorobutanoic acid (PFBA) (CASRN 375-22-4), 3,3,4,4,5,5,6,6,7,7,8,8,8-, tridecafluorooctanesulphonyl chloride (CASRN 27619-89-2) based on 1H,1H, 2H, 2H-perfluorooctane sulfonic acid (6:2 FTS) (CASRN 27619-97-2), and pentafluoropropanoic anhydride (CASRN 356-42-3) based on perfluoropropanoic acid (PFPrA) (CASRN 422-64-0).

2. Additionally, in the event that EPA uses a category approach for TRI PFAS reporting, the Agency is considering whether to expand the categories (*e.g.*, to include additional chemicals related to the acid on which a given category is based, beyond the previously mentioned salts, acyl/sulfonyl halides, and anhydrides), along with data supporting such a listing under EPCRA

313.

3. In this document, EPA has defined category names based on the composition of the categories with the most inclusive identified members. EPA requests comment on whether all category names should refer to salts, acyl/sulfonyl halides, and/or anhydrides related to the acid for which the category is named, or only include salts, acyl/sulfonyl halides, and/or anhydrides where that category specifically identifies such examples as part of the category's composition. For example, the 9Cl-PF3ONS (Unit III.B.1.) and 11Cl-PF3OUdS (Unit III.B.2.) category names, as proposed, are inclusive of potential sulfonyl halides and anhydrides because these chemicals could exist from a chemistry standpoint, but the Agency is unaware of such chemicals being used in commerce. By including potential sulfonyl halides and anhydrides in the category name, if a facility did manufacture, process, or otherwise use such chemicals and triggered TRI reporting requirements for its dealings with those chemicals, then reporting on such chemicals would be part of its reporting on the associated category, along with its dealings with other chemicals in the given category. Naming the categories to be inclusive of acyl/sulfonyl halides and anhydrides will leave room for later addition into the category.

4. EPA welcomes comment on the proposed reporting approach to such categories that, if finalized, would require facilities to calculate thresholds and report the aggregated weights of release and other wastes from all constituents of a PFAS category. This proposed approach is an alternative to a requirement to report the weights of just the parent acid, ion, or other moiety of concern of all chemicals in that category for release and other waste management reporting (such as, for example, the release reporting requirements of metal compound categories or water-dissociable nitrate compounds).

5. EPA seeks comment on whether any of the PFAS being proposed as individual listings should be listed as categories instead (*i.e.*, are any of the proposed individual listings anticipated

to have salts, acyl/sulfonyl halides, an anhydride, or other related substances for which toxicity concerns would be anticipated to be similar to the proposed individually listed chemical?). EPA notes that categories could be formed for an amide and related chemicals (*e.g.*, salts), rather than listing them as individual chemicals, and specifically solicits comment on whether to list PFAS amides as categories similar to the categories including the carboxylic/sulfonic PFAS acids and their salts.

6. EPA seeks comment on whether or not all the proposed categories should include acyl/sulfonyl halides and anhydrides. EPA has included them where known, but there may be some missing, or the Agency may become aware of an acyl/sulfonyl halide or anhydride in the future.

7. EPA seeks comment on the approach of listing a PFAS acid based on its salt. Where hazard data sufficient to support a listing were available for a PFAS salt but not the corresponding non-salt PFAS acid, the Agency could list the PFAS acid based on the toxicity of the salt. This assumes the compound comprising the salt does not contribute its own toxicity separate from the PFAS portion of the chemical. For example, perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt (EEA-NH₄; CASRN 908020-52-0) is individually being proposed for listing. Perfluoro-3,6-dioxaoctanoic acid (CASRN 80153-82-8) is the corresponding PFAS acid, with an expected similar toxicity to the ammonium salt (negligible toxicity expected to be contributed by the NH₄⁺ in the ammonium salt). Note that this also relates to Unit VIII. about PFAS amides and related substances as categories.

8. EPA seeks comment on whether there are PFAS beyond the chemicals identified in this proposal for which available data would be sufficient for a TRI listing. EPA solicits comment on PFAS that the Agency might have overlooked where existing hazard literature would support a finding required by EPCRA 313(d)(2) for a TRI chemical listing, including on

the basis of its expected degradants. Examples of such chemicals include those PFAS specified by the NDAA section 7321(d)(A) through (N), but for which EPA did not find sufficient information supporting a listing pursuant to EPCRA 313(d)(2) criteria which include 8:2 fluorotelomer sulfonic acid (8:2 FTS) (CASRN 39108-34-4) and N-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA) (CASRN 2991-50-6).

For any PFAS that is not included in this EPA proposed rule but which commenters support listing, EPA requests any supporting data of sufficient quality to support an EPCRA 313 listing. In submitting literature for EPA's consideration, please refer to previous TRI chemical listing rule discussions for further guidance on how the Agency determines whether a study or data is sufficient for TRI listing, and whether there is sufficient data support an EPCRA 313 listing: see the Addition of 12 Chemicals final rule (87 FR 73475; November 30, 2022 (Ref. 16)) and the 1994 chemical list expansion final rule (59 FR 61432; November 30, 1994 (Ref. 11)).

EPA is not proposing to list any chemicals based on their being known to cause or their being reasonably 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 (42 U.S.C. 11023(d)(2)(A)). Where EPA noted acute human health effects for a given chemical, the Agency also concluded that a serious or irreversible adverse chronic human health effect or significant adverse effect on the environment of sufficient seriousness existed to support the listing of that chemical. Accordingly, EPA focused on the chronic human health effect and/or effect on the environment in lieu of addressing the "beyond facility site boundaries" requirement in a listing based on a significant adverse acute human health effect. EPA is soliciting comment on any PFAS that is not on the TRI list and that this proposed rule has not included as a candidate that might be added to the TRI list based on a significant adverse acute human health effect. Additionally, information

related to possible exposure to the chemical beyond facility site boundaries is also being requested.

9. EPA seeks comment on its approach using ECOTOX and EPA HAWC projects (and information summarized by other EPA databases in general) for the purpose of supporting chemical listings on TRI (see fulvestrant (CASRN: 129453-61-8) and (1H,1H, 2H, 2H-perfluorooctane sulfonic acid (6:2 FTS) (CASRN 27619-97-2)). EPA also solicits comment on whether other methods of providing evidence to support TRI chemical listings other than listing support documents specifically drafted for the TRI action may be appropriate, such as read-across methods (*i.e.*, applying hazard data from a data-rich source chemical to a related data-poor chemical to determine potential properties or hazards).

10. EPA seeks comment on the 100-pound reporting threshold being proposed for the listing in this rulemaking. Additionally, EPA seeks comment on whether the threshold used for these proposed additions to the TRI list should be aligned with the threshold applicable to PFAS added pursuant to NDAA section 7321(b) and (c).

11. EPA seeks comment on its proposed regulatory framework for establishing PFAS categories encompassing the salts and acyl/sulfonyl halides of future PFAS acids that will be automatically added to the TRI list after a triggering event pursuant to NDAA section 7321(c).

12. EPA requests comment on what nomenclature to use for these categories (*e.g.*, “[acid name], salts and acyl/sulfonyl halides”, “[acid name], salts, acyl/sulfonyl halides, and the anhydride form”, “[acid name] and associated compounds”, or some other convention). For the “associated compounds” nomenclature, EPA would define or interpret “associated compounds” to refer to salts, acyl/sulfonyl halides, and/or anhydrides.

In addition to the requests for comment described in this document, EPA also requests comment on the additional topics identified in this document to help inform potential future TRI

regulatory activities.

13. Since PFAS are ubiquitous in the environment and robust hazard data exist for well-studied PFAS (Ref. 3, 14, 70), EPA is considering additional avenues to expedite adding PFAS to the TRI list. For example, the OECD has described a standardized terminology for defining PFAS and grouping them based on their structural traits (Ref. 7). EPA has developed Markush representations to group and categorize PFAS based on generalized structures (see <https://comptox.epa.gov/dashboard/chemical-lists/PFASMARKUSH>). EPA has also developed PFAS-specific structural representations known as ToxPrints to characterize PFAS by their atom, bond, chain, and functional group to facilitate category development (Ref. 76). More broadly, OECD has published technical guidance for the development, justification and application of category and analogue approaches. These analogue and category approaches are typically underpinned by one or more of the following similarity contexts including structural, physicochemical, metabolic, bioactivity, reactivity and (eco)toxicological similarity. While no single categorization approach will satisfy all needs and the specifics of a given category approach will likely differ depending on the intended application, such grouping approaches are well-established in the scientific literature and are widely applied within the scientific and regulatory community (Ref. 7). These approaches typically categorize PFAS based on foundational understandings of chemistry and toxicity. To this end, EPA is requesting comment on whether the Agency should identify PFAS for which there is a lack of direct evidence to support a TRI listing, but instead base the listing on similarities (*e.g.*, structural similarities) a particular PFAS shares with other PFAS for which there is sufficient evidence, and apply such evidence to the data-poor PFAS. For example, EPA is proposing to add 6:2 fluorotelomer alcohol, 6:2 fluorotelomer sulfonamide betaine, 6:2 fluorotelomer sulfonate ammonium, and 8:2 fluorotelomer sulfonic acid to the TRI list based on available data. It is also aware of other

similar chemical substances such as 3:1 fluorotelomer alcohol, and 4:2 fluorotelomer alcohol. While EPA may not have hazard data specific on these chemicals, it could determine that these listings are appropriate based on generally accepted scientific principles. In this example, data on the chemicals being proposed for listing could be used as sufficient evidence to demonstrate that these other, similar chemicals (*i.e.*, 3:1 fluorotelomer alcohol and 4:2 fluorotelomer alcohol) also meet the criteria for listing on the TRI. EPA posits that X:2 and X:1 fluorotelomer alcohols and their precursors and derivatives, which are expected to break down into the corresponding X-length fluoroalkyl carboxylates, are expected to result in similar adverse effects on human health and the environment as substances already TRI-listed as well as those being proposed for addition to the TRI. EPA is considering the appropriateness of this general approach, as well as means to further speciate its application, for these as well as other categories as described by OECD and other regulatory bodies, including EPA. EPA is soliciting comment on this approach, as well as requesting assistance in identifying additional chemicals to consider based on such an approach.

14. Pursuant to the NDAA, for PFAS added to the TRI list pursuant to NDAA section 7321(b) and (c), EPA must, within five years after the NDAA's enactment, determine whether it is warranted to revise the 100-pound reporting threshold provided by the NDAA for chemicals added to the TRI pursuant to those paragraphs. Accordingly, EPA seeks comment on its proposal to implement a 100-pound reporting threshold for PFAS added to the TRI list pursuant to NDAA section 7321(b) and (c). Similarly, EPA seeks comment on the 100-pound reporting threshold being proposed for the listing in this rulemaking. Further, EPA is soliciting comment on whether the reporting threshold should be consistent across all PFAS on the TRI list, regardless of the specific mechanism that caused their addition to the TRI list.

15. EPA seeks comment on whether documents related to EPA actions other than those

specified in Unit VII. should be identified as events that the Agency interprets as “finaliz[ing] a toxicity value” as that term is used in NDAA section 7321(c)(1)(A)(1).

16. The Agency is soliciting comment on the listing support documents specifically prepared for this action and whether they justify its proposed determination that there is sufficient evidence to establish that one or more of the criteria for listing under EPCRA section 313(d)(2) have been met.

IX. 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. U.S. Environmental Protection Agency (September 2024). Economic Analysis for the Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting; Proposed Rule (RIN 2070-AL03).

2. U.S. Environmental Protection Agency (2023). TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Final Rule. 88 FR 70516 (October 11, 2023 (FRL-7902-02-OCSP)). <https://www.govinfo.gov/content/pkg/FR-2023-10-11/pdf/2023-22094.pdf>

3. U.S. Environmental Protection Agency. *Our current understanding of the human health and environmental risks of PFAS*. 2022. <https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas>

4. Agency for Toxic Substances and Disease Registry (2021). Toxicological Profile for

Perfluoroalkyls. U.S. Department of Health and Human Services. <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>

5. Agency for Toxic Substances and Disease Registry. *Per- and Polyfluoroalkyl Substances (PFAS) and Your Health. PFAS in the U.S. Population*. June 2023. <https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html>

6. Centers for Disease Control and Prevention (2015). Fourth National Report on Human Exposure to Environmental Chemicals. Department of Health and Human Services. https://www.cdc.gov/biomonitoring/pdf/fourthreport_updatedtables_feb2015.pdf

7. Organisation for Economic Co-Operation and Development (2021). Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. Series on Risk Management. No.61. Environment Directorate Chemicals and Biotechnology Committee. [https://one.oecd.org/document/ENV/CBC/MONO\(2021\)25/en/pdf](https://one.oecd.org/document/ENV/CBC/MONO(2021)25/en/pdf)

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9. U.S. Environmental Protection Agency. *CompTox Chemicals Dashboard*. 2021. <https://comptox.epa.gov/dashboard/>

10. U.S. Environmental Protection Agency. *EPA PFAS chemicals without explicit structures. CompTox Chemicals Dashboard*. August 2021. <https://comptox.epa.gov/dashboard/chemical-lists/PFASDEV1>

11. U.S. Environmental Protection Agency (1994). Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know; Final Rule. 59 FR 61432 (November 30, 1994 (FRL-4922-2)).

12. U.S. Environmental Protection Agency. *ECOTOX Knowledgebase*. September 2023.

<https://cfpub.epa.gov/ecotox/>

13. U.S. Environmental Protection Agency. *EPA Health Assessment Workspace Collaborative (EPA HAWC): ORD SEM PFAS 150*. 2022. <https://hawc.epa.gov/assessment/100500085/>

14. Carlson, L.M., *et al.* (2022). Systematic Evidence Map for Over One Hundred and Fifty Per- and Polyfluoroalkyl Substances (PFAS). *Environmental Health Perspectives* 130(5):p. 056001. <https://doi.org/10.1289/EHP10343>

15. Olker, J.H., *et al.* (2022). The ECOTOXicology Knowledgebase: A Curated Database of Ecologically Relevant Toxicity Tests to Support Environmental Research and Risk Assessment. *Environmental Toxicology and Chemistry* 41(6):p. 1520-1539. <https://doi.org/10.1002/etc.5324>

16. U.S. Environmental Protection Agency (2022). Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting. 87 FR 73475 (November 30, 2022 (FRL-5927-02-OCSP)).

17. U.S. Environmental Protection Agency (2023). TRI Listing Analysis for Perfluoroheptanesulfonic acid (PFHpS) (CASRN 375-92-8).

18. Interstate Technology Regulatory Council (2023). Chemistry, Terminology, and Acronyms: Introduction to the PFAS Family. https://pfas-1.itrcweb.org/2-2-chemistry-terminology-and-acronyms/#2_2_2

19. U.S. Environmental Protection Agency. *PFAS Environmental Reaction Library Version 1.1: Hydrolysis Schemes*. July 2022. https://qed.epa.gov/static_qed/cts_app/docs/PFAS%20HTML/PFASEnvironmentalReactionLibrary_ver1-1.htm#EnvLib_Scheme_6

20. U.S. Environmental Protection Agency (2023). Human Health Hazard TRI Listing Support Document for 9-Chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS)

(CASRN 756426-58-1).

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22. U.S. Environmental Protection Agency (2023). Ecological Hazard TRI Listing Support Document for 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS) (CASRN 763051-92-9).

23. U.S. Environmental Protection Agency (2021). Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). Office of Water. https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf

24. U.S. Environmental Protection Agency (2021). Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). Office of Research and Development, Center for Public Health and Environmental Assessment. <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888>

25. U.S. Environmental Protection Agency (2022). IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salts. Office of Research and Development, Center for Public Health and Environmental Assessment. EPA/600/R-20/345F. https://iris.epa.gov/ChemicalLanding/&substance_nmbr=701

26. U.S. Environmental Protection Agency (2024). IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts. Office of Research and Development, Center for Public Health and Environmental Assessment. https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549465

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28. National Toxicology Program (NTP) (2016). NTP Monograph: Immunotoxicity associated with exposure to perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS). Research Triangle Park, NC: U.S. Department of Health and Human Services, Office of Health Assessment and Translation. https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf
29. U.S. Environmental Protection Agency (2022). Review of EPA's analyses to support EPA's national primary drinking water rulemaking for PFAS (EPA-SAB-22-008). https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::18:P18_ID:2601
30. U.S. Environmental Protection Agency (2023). Human Health Hazard TRI Listing Support Document for Perfluorododecanoic acid (PFDoA) (CASRN 307-55-1).
31. U.S. Environmental Protection Agency (2023). IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS) and Related Salts (Public Comment and External Review Draft). Office of Research and Development, Center for Public Health and Environmental Assessment. https://iris.epa.gov/ChemicalLanding/&substance_nmbr=705
32. U.S. Environmental Protection Agency (2023). IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts. Office of Research and Development, Center for Public Health and Environmental Assessment. https://iris.epa.gov/ChemicalLanding/&substance_nmbr=704
33. U.S. Environmental Protection Agency (2023). PFAS National Primary Drinking Water Regulation; Final Rule. 89 FR 32532 (April 26, 2024 (FRL 8543-02-OW)). <https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027>

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X. What are the Statutory and Executive Orders reviews associated with this action?

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an economic analysis of the potential impacts associated with this action. This analysis, “Economic Analysis” (Ref. 1) is also available in the docket and summarized in Unit I.D.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2796.01 and OMB Control No. 2070-NEW (Ref. 77). You can find a copy of the ICR in the docket, and it is briefly summarized here.

Facilities subject to the reporting requirements under EPCRA section 313 and PPA section 6607 may use either EPA Toxic Chemicals Release Inventory Form R (EPA Form 9350-

1), or EPA Toxic Chemicals Release Inventory Form A (EPA Form 9350- 2). The Form R must be completed if a facility manufactures, processes, or otherwise uses any listed chemical above threshold quantities and meets certain other criteria. For the Form A, EPA established an alternative threshold for facilities with low annual reportable amounts of a listed toxic chemical. A facility that meets the appropriate reporting thresholds, but estimates that the total annual reportable amount of the chemical does not exceed 500 pounds per year, can take advantage of an alternative manufacture, process, or otherwise use threshold of 1 million pounds per year of the chemical, provided that certain conditions are met, and submit the Form A instead of the Form R. In addition, respondents may designate the specific chemical identity of a substance as a trade secret pursuant to EPCRA section 322, 42 U.S.C. 11042, 40 CFR part 350.

Respondents/affected entities: Facilities covered under EPCRA section 313 that manufacture, process or otherwise use listed PFAS see Unit I.A.

Respondent's obligation to respond: Mandatory per EPCRA 313

Estimated number of respondents: 356 to 1,110

Frequency of response: annually.

Total estimated burden: 26,693 to 83,229 burden hours in the first year and approximately 12,711 to 39,633 burden hours in the steady state (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Approximately \$2,114,886 to \$6,594,234 in the first year of the reporting and approximately \$1,007,093 to \$3,140,123 includes \$0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rule. EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular ICR by selecting "Currently under Review — Open for Public Comments" or by using the search function. OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are small manufacturing facilities. The Agency has determined that of the 356 to 1,110 entities estimated to be impacted by this action, 277 to 865 are small businesses; no small governments or small organizations are expected to be affected by this action. The average cost per small firm is \$6,338 (at a 2% discount rate). All small businesses affected by this action are estimated to incur annualized cost impacts of less than 1%. Even under a worst-case scenario comparing compliance costs to average revenue of firms with between 10 (smallest number required to report) and 14 employees instead of comparing compliance costs to the weighted average revenue of small firms, there are still no costs that exceed the 1% impact threshold. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities. A more detailed analysis of the impacts on small entities is provided in EPA's economic analysis (Ref. 1).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described

in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. As indicated previously, EPA estimates the costs of this action will be approximately \$2,114,886 and \$6,594,234 in the first year of reporting and approximately \$1,007,093 and \$3,140,123 in the subsequent years (Ref. 1).

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. It does not have substantial direct effects on tribal government because this action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of Executive Order 13045.

Since this is not a “covered regulatory action,” EO 13045 does not apply. However, the

Policy on Children's Health does apply. Although this action does not concern an environmental health or safety risk, the data collected as a result of this action will provide information about releases to the environment that could be used to inform the public on potential exposures to toxic chemical releases, pursuant to the right-to-know principles. EPA also believes that the information obtained as a result of this action could be used by government agencies, researchers, and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential exposures and related human health or environmental risks identified as a result of increased knowledge of exposures to PFAS.

H. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

I. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that this type of action does not directly impact human health or environmental conditions. Although this action does not directly impact human health or environmental conditions, EPA identifies and addresses environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023) by requiring reporting. This regulatory action makes changes to the reporting requirements for PFAS that will result in more information being collected and provided to the public. By requiring reporting of this additional information, EPA provides communities across the U.S. (including communities with environmental justice concerns) with access to data which they may then use to seek lower exposures and consequently reduce chemical risks for themselves and their children. This information can also be used by

government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, the informational benefits of the action will have a positive impact on the human health and environmental impacts on communities with environmental justice concerns.

J. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

List of Subjects in 40 CFR Part 372

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

Dated: October 1, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble; EPA is proposing to amend 40 CFR chapter I as follows:

PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW

1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

2. In § 372.28:

a. Revise in “Table 1 to Paragraph (a)(1)” the entry for “Per- and polyfluoroalkyl substances”; and

b. Add alphabetically in “Table 2 to Paragraph (a)(2)” an entry for “Per- and polyfluoroalkyl substances”.

The revision and addition read as follows:

§ 372.28 Lower thresholds for chemicals of special concern.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Chemical name	CAS No.	Reporting threshold (in pounds)
* * * * *		
Per- and polyfluoroalkyl substances (Individually listed chemicals added by 15 U.S.C. 8921(b)(1) and (c)(1) and pursuant to 42 U.S.C. 11023(d)(2)). (EPA periodically updates the lists of covered chemicals at §372.65(d) and (e) to reflect chemicals that have been added by 15 U.S.C. 8921).	see §372.65(d) and (e).	100
* * * * *		

(2) * * *

Table 2 to Paragraph (a)(2)

Category name	Reporting threshold (in pounds)
* * * * *	
Per- and polyfluoroalkyl substances (Chemical categories added by 15 U.S.C. 8921 (b)(1) and (c)(1) and pursuant to 42 U.S.C. 11023(d)(2)). (EPA periodically updates the lists of covered chemicals at §372.65(f) to reflect chemical categories that have been added by 15 U.S.C. 8921).	100
* * * * *	

3. In § 372.65:

a. Revise the introductory text paragraph;

b. Remove in “Table 4 to Paragraph (d)” the entries for “Ammonium perfluorobutanoate”; “Ammonium perfluorooctanoate”; “Chromium(III) perfluorooctanoate”; “Ethanaminium, N,N,N-triethyl-, salt with 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-1-octanesulfonic acid (1:1)”; “Hexafluoropropylene oxide dimer acid”; “Hexafluoropropylene oxide dimer acid ammonium salt”; “1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt”; “1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt”; “1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, compd. with ’,2'-iminobis[ethanol] (1:1)”; “Lithium (perfluorooctane)sulfonate”; “1-Octanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-, ammonium salt”; “Octanoyl fluoride, pentadecafluoro-“-;-”; “Perfluorobutane sulfonic acid”; “Perfluorobutanesulfonate”; “Perfluorobutanoate”; “Perfluorobutanoic acid”; “Perfluorodecanoic acid”; “Perfluorododecanoic acid”; “Perfluorohexanesulfonic acid”; “Perfluorononanoic acid”; “Perfluorooctane sulfonic acid”; and “Perfluorooctanoic acid”; “Perfluorooctylsulfonyl fluoride”; “Potassium heptafluorobutanoate”; “Potassium perfluorobutane sulfonate”; “Potassium perfluorooctanesulfonate”; “Potassium perfluorooctanoate”; “Silver(I) perfluorooctanoate”; “Sodium perfluorobutanoate”; and “Sodium perfluorooctanoate”;

c. Add in “Table 4 to Paragraph (d)”, in alphabetical order, entries for “Broflanilide”; “1-

Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-"; "1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-"; "Cyclopentene, 1,3,3,4,4,5,5-heptafluoro-"; "Ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt"; "6:2 Fluorotelomer alcohol"; "Fulvestrant"; "Hexaflumuron"; "Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)-"; "Perfluorotridecanoic acid"; "Perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt"; "2-Propenoic acid, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl ester"; "Pyrifluquinazon"; "Tetraconazole"; "Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tri-deca-fluorooctyl)silane"; and "Trifluoro(trifluoromethyl)oxirane".";

d. Remove in "Table 5 to Paragraph (e)" the entries for "307-35-7"; "307-55-1"; "335-66-0"; "335-67-1"; "335-76-2"; "335-93-3"; "335-95-5"; "355-46-4"; "375-22-4"; "375-73-5"; "375-95-1"; "1763-23-1"; "2218-54-4"; "2395-00-8"; "2795-39-3"; "2966-54-3"; "3825-26-1"; "3871-99-6"; "10495-86-0"; "13252-13-6"; "29081-56-9"; "29420-49-3"; "29457-72-5"; "45048-62-2"; "45187-15-3"; "56773-42-3"; "62037-80-3"; "68141-02-6"; "68259-08-5"; and "70225-16-0";

e. Add in "Table 5 to Paragraph (e)", in numerical order, the entries for "428-59-1"; "647-42-7"; "1892-03-1"; "34454-97-2"; "51851-37-7"; "67584-55-8"; "68298-12-4"; "72629-94-8"; "86479-06-3"; "112281-77-3"; "129453-61-8"; "132182-92-4"; "132843-44-8"; "337458-27-2"; "908020-52-0"; and "1207727-04-5"; and

f. Add paragraph (f) and "Table 6 to Paragraph (f)" for "per-and polyfluoroalkyl chemical category listing".

The revisions and additions read as follows:

§ 372.65 Chemicals and chemical categories to which this part applies.

The requirements of this part apply to the chemicals and chemical categories listed in this

section. This section contains six listings. Paragraph (a) of this section is an alphabetical order listing of those chemicals that have an associated Chemical Abstracts Service (CAS) Registry number. Paragraph (b) of this section contains a CAS number order list of the same chemicals listed in paragraph (a) of this section. Paragraph (c) of this section contains the chemical categories for which reporting is required. These chemical categories are listed in alphabetical order and do not have CAS numbers. Paragraph (d) of this section is an alphabetical order listing of the per- and polyfluoroalkyl substances and their associated CAS Registry number. Paragraph (e) of this section contains a CAS number order list of the same chemicals listed in paragraph (d) of this section. Each listing identifies the effective date for reporting under § 372.30. Paragraph (f) of this section is an alphabetical order listing of the per- and polyfluoroalkyl substances chemical categories for which reporting is required. Per- and polyfluoroalkyl substances automatically added to the list of chemicals for which reporting is required pursuant to the Fiscal Year 2020 National Defense Authorization Act, section 7321(c), shall be incorporated as chemical categories to include the acid and associated salts, acyl/sulfonyl halides, and anhydride of that acid if added pursuant to a published final toxicity value that provides toxicity values for an acid and associated salts and/or acyl/sulfonyl halides and/or anhydride.

* * * * *

(d) * * *

Table 4 to Paragraph (d)

Chemical Name	CAS No.	Effective date
* * * * *		
Broflanilide	1207727-04-5	1/1/2025
* * * * *		
1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-	34454-97-2	1/1/2025
* * * * *		
1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-	68298-12-4	1/1/2025

Chemical Name	CAS No.	Effective date
* * * * *		
Cyclopentene, 1,3,3,4,4,5,5-heptafluoro-	1892-03-1	1/1/2025
* * * * *		
Ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt	132843-44-8	1/1/2025
* * * * *		
6:2 Fluorotelomer alcohol	647-42-7	1/1/2025
* * * * *		
Fulvestrant	129453-61-8	1/1/2025
* * * * *		
Hexaflumuron	86479-06-3	1/1/2025
* * * * *		
Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)-	132182-92-4	1/1/2025
* * * * *		
Perfluorotridecanoic acid	72629-94-8	1/1/2025
* * * * *		
Perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt	908020-52-0	1/1/2025
* * * * *		
2-Propenoic acid, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl ester	67584-55-8	1/1/2025
* * * * *		
Pyrifluquinazon	337458-27-2	1/1/2025
* * * * *		
Tetraconazole	112281-77-3	1/1/2025
* * * * *		
Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tri-decafluorooctyl)silane	51851-37-7	1/1/2025
* * * * *		
Trifluoro(trifluoromethyl) oxirane	428-59-1	1/1/2025
* * * * *		

(e) * * *

Table 5 to Paragraph (e)

CAS No.	Chemical Name	Effective date
* * * * *		
428-59-1	Trifluoro(trifluoromethyl) oxirane	1/1/2025
* * * * *		
647-42-7	6:2 Fluorotelomer alcohol	1/1/2025
* * * * *		
1892-03-1	Cyclopentene, 1,3,3,4,4,5,5-heptafluoro-	1/1/2025
* * * * *		

CAS No.	Chemical Name	Effective date
34454-97-2	1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl-	1/1/2025
* * * *	* * *	
51851-37-7	Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane	1/1/2025
* * * *	* * *	
67584-55-8	2-Propenoic acid, 2-[methyl[(nonafluorobutyl)sulfonyl]amino]ethyl ester	1/1/2025
* * * *	* * *	
68298-12-4	1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl-	1/1/2025
* * * *	* * *	
72629-94-8	Perfluorotridecanoic acid	1/1/2025
* * * *	* * *	
86479-06-3	Hexaflumuron	1/1/2025
* * * *	* * *	
112281-77-3	Tetraconazole	1/1/2025
* * * *	* * *	
129453-61-8	Fulvestrant	1/1/2025
* * * *	* * *	
132182-92-4	Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)-	1/1/2025
* * * *	* * *	
132843-44-8	Ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl)sulfonyl]-, lithium salt	1/1/2025
* * * *	* * *	
337458-27-2	Pyrifluquinazon	1/1/2025
* * * *	* * *	
908020-52-0	Perfluoro(2-ethoxy-2-fluoroethoxy)acetic acid ammonium salt	1/1/2025
* * * *	* * *	
1207727-04-5	Broflanilide	1/1/2025
* * * *	* * *	

(f) Per-and polyfluoroalkyl chemical category listing.

Table 6 to Paragraph (f)

Category Name	Effective date
9-chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS) (CASRN 756426-58-1), salts, sulfonyl halides, and anhydride (includes all associated salts and sulfonyl halides, including the following): 73606-19-6: potassium 9-chlorohexadecafluoro-3-oxanonane-1 sulfonate.	1/1/2025
11-chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-PF3OUdS) (CASRN 763051-92-9), salts, sulfonyl halides, and anhydride (includes all	1/1/2025

associated salts and sulfonyl halides, including the following): 83329-89-9: potassium 11-chloroeicosafluoro-3-oxaundecane-1-sulfonate.	
Hexafluoropropylene oxide dimer acid (HFPO-DA, GenX) (CASRN 13252-13-6), salts, and acyl halides (includes all associated salts and acyl halides, including the following): 2062-98-8: propanoyl fluoride, 2,3,3,3-tetrafluoro-2 (heptafluoropropoxy)-]. 62037-80-3: ammonium perfluoro-2-methyl-3-oxahexanoate. 67118-55-2: potassium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate. 67963-75-1: sodium 2,3,3,3-tetrafluoro-2(heptafluoropropoxy)propanoate.	1/1/2025
Perfluorobutanesulfonic acid (PFBS), salts, sulfonyl halides, and anhydride (CASRN 375-73-5) (includes all associated salts and sulfonyl halides, including the following): 375-72-4: perfluorobutanesulfonyl fluoride. 29420-49-3: potassium perfluorobutane sulfonate. 36913-91-4: perfluorobutanesulfonic anhydride. 60453-92-1: sodium nonafluorobutane-1-sulfonate. 68259-10-9: ammonium perfluorobutanesulfonate. 70225-18-2: bis(2-hydroxyethyl)ammonium perfluorobutanesulfonate. 131651-65-5: lithium nonafluorobutane-1-sulfonate. 220689-12-3: tetrabutylphosphonium perfluorobutanesulfonate. 507453-86-3: magnesium nonafluorobutanesulfonate.	1/1/2025
Perfluorobutanoic acid (PFBA) (CASRN 375-22-4), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following): 335-42-2: perfluorobutanoyl fluoride. 336-59-4: perfluorobutanoic anhydride. 375-16-6: heptafluorobutyryl chloride. 2218-54-4: sodium perfluorobutanoate. 2966-54-3: potassium perfluorobutanoate. 3794-64-7: silver heptafluorobutyrate. 10495-86-0: ammonium perfluorobutanoate. 73755-28-9: rhodium(II) perfluorobutyrate dimer.	1/1/2025
Perfluorodecanoic acid (PFDA) (CASRN 335-76-2), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following): 307-38-0: perfluorodecanoyl chloride. 3108-42-7: ammonium Perfluorodecanoate. 3830-45-3: sodium Perfluorodecanoate. 942199-24-8: perfluorodecanoic anhydride.	1/1/2025
Perfluorododecanoic acid (PFDoA) (CASRN 307-55-1), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following): 3793-74-6: ammonium tricosafuorododecanoate. 1456735-80-0: perfluorododecanoic anhydride.	1/1/2025
Perfluorohexanesulfonic acid (PFHxS) (CASRN 355-46-4), salts, sulfonyl	1/1/2025

<p>halides, and anhydride (includes all associated salts and sulfonyl halides, including the following):</p> <ul style="list-style-type: none"> 423-50-7: perfluorohexanesulfonyl fluoride. 3871-99-6: potassium perfluorohexanesulfonate. 55120-77-9: lithium perfluorohexanesulfonate. 68259-08-5: ammonium perfluorohexanesulfonate. 70225-16-0: bis(2-hydroxyethyl)ammonium perfluorohexanesulfonate. 82382-12-5: sodium perfluorohexanesulfonate. 109065-55-6: perfluorohexanesulfonic anhydride. 	
<p>Perfluorohexanoic acid (PFHxA) (CASRN 307-24-4), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following):</p> <ul style="list-style-type: none"> 308-13-4: perfluorohexanoic anhydride. 336-02-7: silver perfluorohexanoate. 355-38-4: perfluorohexanoyl fluoride. 335-53-5: perfluorohexanoyl chloride. 2923-26-4: sodium perfluorohexanoate. 3109-94-2: potassium undecafluorohexanoate. 21615-47-4: ammonium perfluorohexanoate. 	1/1/2025
<p>Perfluorononanoic acid (PFNA) (CASRN 375-95-1), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following):</p> <ul style="list-style-type: none"> 558-95-2: heptadecafluorononanoyl fluoride. 4149-60-4: ammonium perfluorononanoate. 21049-38-7: potassium perfluorononanoate. 21049-39-8: sodium heptadecafluorononanoate. 52447-23-1: heptadecafluorononanoyl chloride. 228407-54-3: perfluorononanoic anhydride. 	1/1/2025
<p>1H,1H, 2H, 2H-Perfluorooctane sulfonic acid (6:2 FTS) (CASRN 27619-97-2), salts, sulfonyl halides, and anhydride (includes all associated salts and sulfonyl halides, including the following):</p> <ul style="list-style-type: none"> 2043-57-4: 1H,1H,2H,2H-Perfluorooctyl iodide. 27619-89-2: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulphonyl chloride. 27619-94-9: sodium 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctane-1-sulfonate. 59587-38-1: potassium 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctanesulfonate. 59587-39-2: 6:2 fluorotelomer sulfonate ammonium. 1807944-82-6: 1-octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-, barium salt (2:1). 	1/1/2025
<p>Perfluorooctanoic acid (PFOA) (CASRN 335-67-1), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following):</p> <ul style="list-style-type: none"> 335-64-8: pentadecafluorooctanoyl chloride. 335-66-0: pentadecafluorooctanoyl fluoride. 335-93-3: silver perfluorooctanoate. 	1/1/2025

<p>335-95-5: sodium perfluorooctanoate. 2395-00-8: potassium perfluorooctanoate. 3825-26-1: ammonium perfluorooctanoate. 17125-58-5: lithium perfluorooctanoate. 17125-60-9: cesium perfluorooctanoate. 33496-48-9: perfluorooctanoic anhydride. 68141-02-6: chromium perfluorooctanoate. 98065-31-7: potassium pentadecafluorooctanoate--water (1:1:2).</p>	
<p>Perfluorooctanesulfonic acid (PFOS) (CASRN 1763-23-1), salts, sulfonyl halides, and anhydride (includes all associated salts and sulfonyl halides, including the following): 307-35-7: perfluorooctylsulfonyl fluoride. 423-92-7: perfluorooctanesulfonic anhydride. 2795-39-3: potassium perfluorooctanesulfonate. 4021-47-0: sodium perfluorooctanesulfonate. 29081-56-9: ammonium perfluorooctanesulfonate. 29457-72-5: lithium perfluorooctanesulfonate. 56773-42-3: tetraethylammonium perfluorooctanesulfonate. 70225-14-8: 1-octanesulfonic acid,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluoro-, compd. with 2,2'-iminobis[ethanol] (1:1). 91036-71-4: magnesium bis(heptafluorooctanesulfonate). 111873-33-7: tetrabutylammonium perfluorooctanesulfonate.</p>	1/1/2025
<p>Perfluoropropanoic acid (PFPrA) (CASRN 422-64-0), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following): 356-42-3: pentafluoropropanoic anhydride. 378-76-7: potassium perfluoropropanoate. 378-77-8: sodium perfluoropropanoate. 422-59-3: perfluoropropanoyl chloride. 422-61-7: perfluoropropanoyl fluoride.</p>	1/1/2025
<p>Perfluoroundecanoic acid (PFUnA) (CASRN 2058-94-8), salts, acyl halides, and anhydride (includes all associated salts and acyl halides, including the following): 4234-23-5: ammonium perfluoroundecanoate. 30377-53-8: potassium perfluoroundecanoate. 60871-96-7: sodium perfluoroundecanoate. 97163-17-2: calcium perfluoroundecanoate. 942199-03-3: perfluoroundecanoic anhydride.</p>	1/1/2025

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