# EPA Proposes to Add 16 PFAS and 15 PFAS Categories to the TRI List of Chemicals

Article By:

Lynn L. Bergeson

Lisa M. Campbell

The U.S. Environmental Protection Agency (EPA) proposed on October 8, 2024, to add 16 individual per- and polyfluoroalkyl substances (PFAS) and 15 PFAS categories representing more than 100 individual PFAS 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). <u>89 Fed. Reg. 81776</u>. The proposed rule also addresses how PFAS categories should be treated. Separately, the proposed rule discusses what events may trigger the automatic addition of a PFAS to the TRI pursuant to the NDAA. EPA notes that this discussion does not propose to list chemicals to the TRI pursuant to the NDAA, but rather describes what EPA documents and activities involving PFAS would trigger an automatic addition under the NDAA. Comments are due **December 9, 2024**. According to EPA, 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 the comments by **November 7, 2024**.

#### Background

The NDAA provides several avenues for PFAS to be added to the TRI:

- Section 7321(b), "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), "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. These events include: EPA issuing a final toxicity value for a PFAS; including a PFAS in a significant new use rule (SNUR) issued under the Toxic Substances Control Act (TSCA) or adding a PFAS to an existing SNUR; and designating a PFAS as active on the TSCA Inventory.
- Section 7321(d) requires EPA to determine within two years of the date of enactment of the NDAA whether certain PFAS (including classes) meet any of the listing criteria of EPCRA Section 313(d)(2). As stated in NDAA Section 7321(d)(2), 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) 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.

## Technical Evaluation of the Toxicity of the PFAS Being Proposed for Addition

According to the proposed rule, EPA used a combination of existing Agency human health assessments and listing support documents specifically prepared for this rulemaking to evaluate the available data on human health effects and/or environmental effects associated with the PFAS being proposed for listing. EPA developed listing support documents created specifically for this rulemaking "with the TRI listing criteria in mind" and states that they "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 Office of Chemical Safety and Pollution Prevention (OCSPP), one from the Office of Research and Development (ORD), and one from the Office of Land and Emergency Management (OLEM). EPA notes that, furthermore, review often included multiple additional scientists from the same office and that relevant assessments were also reviewed by scientists in the Office of Water (OW). EPA requests 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.

EPA proposes to use the following Agency databases that have evaluated and summarized hazard and dose-response literature as a basis for listing additional PFAS: the EPA Health Assessment Workspace Collaborative project for the Systematic Evidence Map for Over One Hundred and Fifty Per- and Polyfluoroalkyl Substances publication (EPA HAWC PFAS 150) and the ECOTOX Knowledgebase (ECOTOX). For such proposed listings, EPA states that it 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." According to the proposed rule, "EPA considers this approach a more efficient means of informing additions to the TRI chemical list and solicits comment on this approach." Because this would constitute a shift in relying on interpretation of extracted and curated data in a knowledge delivery platform rather than a formal listing support document for TRI listing purposes, EPA requests comment on this approach before expanding its use for future listings. EPA notes that whether it generates a listing support document, relies on a formal hazard assessment, or interprets curated data provided by a platform such as ECOTOX or projects in EPA HAWC, "it will review and describe the toxicity information so as to justify its finding of sufficient evidence to support a EPCRA [Section] 313(d)(2) listing criteria finding."

# Chemicals on the TRI List Are Being Reclassified as Chemical Categories

The proposed rule notes that category reporting would require a facility to submit only one form for a category, which accounts for activities and quantities associated with all member chemicals. First facilities would calculate the total weight of all chemicals that fall under a category for each threshold activity (*i.e.*, manufacture, process, and otherwise use) and then 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, the facility would be required to report the aggregated quantities of releases and other waste management activities of the chemicals in that chemical category.

EPA notes that under the proposed rule, it is possible for a PFAS category to be inclusive of a PFAS that has a confidential business information (CBI) claim related to its identity, and states that "in which case, it would need to be reported as part of that category." According to the proposed rule, for reviewing toxicity data to support TRI listings, EPA 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. Because reporting a TRI category requires a facility to report only the category name and not the specific individual members, it is possible a facility may meet reporting requirements for a PFAS category based on activities involving a PFAS with a CBI claim. EPA states that "the reporting form would only reveal the broader category name and would not divulge the individual chemicals of that category involved," however, and that "it does not anticipate this scenario to be likely."

## **Reporting Threshold for PFAS Proposed for Listing**

For PFAS added to the EPCRA Section 313 toxic chemical list under the provisions of NDAA Section 7321(b) and (c), EPA states that Congress established a manufacture, processing, and otherwise use reporting threshold of 100 pounds (lb) for each of the listed PFAS. The 100-lb reporting threshold reflects a concern for small quantities of PFAS due to their toxicity and persistence in the environment. According to EPA, the PFAS proposed for addition have similar properties as those added by the other sections of the NDAA. 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)), EPA proposes to establish a 100-lb manufacture, processing, and otherwise use reporting threshold for the PFAS proposed for addition. EPA requests comment 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 lbs for these PFAS, EPA seeks comment on whether to modify the reporting threshold for other TRI-listed PFAS accordingly.

EPA advises facilities that some PFAS being proposed for listing may fall under multiple TRI chemical categories. EPA states that, for example, silver heptafluorobutyrate (Chemical Abstracts Service Registry Number<sup>®</sup> (CAS RN<sup>®</sup>) 3794-64-7) is being proposed as a member of the Perfluorobutanoic Acid (PFBA), Salts, Acyl Halides, and Anhydride category. Because of the silver constituent in the compound, it is also included in the silver compounds category. EPA notes that 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 that has manufactured that compound must apply the same compound to threshold determinations for each listed category separately and determine whether the 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.

#### Designating PFAS Being Proposed for Addition as Chemicals of Special Concern

EPA proposes to add all of the PFAS described in Unit III of the proposed rule to the list of chemicals of special concern at 40 C.F.R. Section 372.28. Chemicals of special concern have reporting thresholds of either ten or 100 lbs depending on their persistent and bioaccumulative properties. 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.

As reported in our October 24, 2023, <u>blog item</u>, EPA previously eliminated an exemption that allowed facilities to avoid reporting information on certain PFAS when those chemicals were used in small concentrations. <u>88 Fed. Reg. 74360</u> (Oct. 31, 2023). The final rule added PFAS subject to reporting under EPCRA and the PPA pursuant to the NDAA to the list of Lower Thresholds for Chemicals of Special Concern (chemicals of special concern). While these PFAS already had a lower reporting activity threshold of 100 lbs, their addition to the list of chemicals of special concern means such PFAS are subject to the same reporting requirements as other chemicals of special concern (*i.e.*, it eliminates the use of the *de minimis* exemption and the option to use Form A and limits the use of range reporting for PFAS). The final rule removed the availability of the *de minimis* exemption for purposes of the Supplier Notification Requirements for all chemicals on the list of chemicals of special concern, "help[ing] ensure that purchasers of mixtures and trade name products containing such chemicals are informed of their presence in mixtures and products they purchase to better inform any TRI reporting obligations."

# Clarifying the Framework for NDAA Section 7321(c) Additions

According to EPA, 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 Section 7321(c) are deemed added to the TRI list on January 1 of the year after those criteria are met. EPA states that the criteria that lead to listing pursuant to NDAA Section 7321(c) are:

- Final Toxicity Value. The date on which the Administrator approves a final toxicity value for the PFAS or class of PFAS;
- 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.

EPA states that for purposes of identifying PFAS that are automatically added to the TRI list following an event specified under NDAA Section 7321(c), it 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). According to EPA, "[t]his 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."

#### **Request for Comment**

EPA specifically requests public comment on the following topics:

- 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 its 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.
- In the event that EPA uses a category approach for TRI PFAS reporting, EPA 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 Section 313.
- 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.
- EPA welcomes comment on the proposed reporting approach to such categories that, if adopted in final, would require facilities to calculate thresholds and report the aggregated weights of release and other wastes from all constituents of a PFAS category. EPA states that 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).
- EPA seeks comment on whether any of the PFAS being proposed as individual listings should be listed as categories instead (*i.e.*, if any of the proposed individual listings are 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.
- EPA seeks comment on whether all the proposed categories should include acyl/sulfonyl halides and anhydrides. EPA states that it has included them where known, but notes that "there may be some missing, or the Agency may become aware of an acyl/sulfonyl halide or anhydride in the future."
- EPA seeks comment on the approach of listing a PFAS acid based on its salt. EPA states that
  where hazard data sufficient to support a listing were available for a PFAS salt but not the
  corresponding non-salt PFAS acid, EPA 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.
- EPA seeks comment on whether there are PFAS beyond the chemicals identified in the proposed rule for which available data would be sufficient for a TRI listing. EPA solicits comment on PFAS that it might have overlooked where existing hazard literature would support a finding required by EPCRA Section 313(d)(2) for a TRI chemical listing, including on the basis of its expected degradants. For any PFAS that is not included in the proposed rule but which commenters support listing, EPA requests any supporting data of sufficient quality to support an EPCRA Section 313 listing.
- 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. 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).

- EPA seeks comment on the 100-lb 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).
- 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).
- 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.
- EPA states that "[s]ince PFAS are ubiquitous in the environment and robust hazard data exist for well-studied PFAS," it is considering additional avenues to expedite adding PFAS to the TRI list. According to EPA, "[w]hile 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." EPA requests comment on whether it 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.
- 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-lb 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-lb reporting threshold for PFAS added to the TRI list pursuant to NDAA Section 7321(b) and (c). Similarly, EPA seeks comment on the 100-lb reporting threshold being proposed for the listing in this rulemaking. Further, EPA requests 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.
- EPA seeks comment on whether documents related to EPA actions other than those specified in Unit VII of the proposed rule should be identified as events that EPA interprets as "finaliz[ing] a toxicity value" as that term is used in NDAA Section 7321(c)(1)(A)(1).
- EPA requests 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.

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

#### Commentary

Bergeson & Campbell, P.C. (B&C<sup>®</sup>) generally agrees with EPA's proposals. We were pleased to see that EPA is expanding its use of category-based approaches as it has done for decades with <u>new</u> <u>chemical substances</u> under Section 5 of TSCA and more recently with <u>existing chemical substances</u> under Section 6 of TSCA. We were also pleased to see that EPA intends on specifying certain PFAS inclusive of the acid, salts, acyl halides, and anhydrides as the reportable categories rather than a much broader, all-inclusive category. With the proposed category approach, EPA has a better information set upon which to build its argument for TRI listing. Rather than applying data from one class of PFAS (*e.g.*, perfluoroctanoic acid (PFOA)) to a very different one (*e.g.*, fluoropolymers), EPA is grouping substances based on the length of the perfluoro chain (*e.g.*, C8) and head groups that readily interconvert (acyl halide to acid to salt). We do, however, have concerns about EPA's proposal to use summarized information from databases to support TRI listings. We provide examples below to illustrate our concerns.

EPA <u>describes</u> ECOTOX as "a reliable source of curated ecological toxicity data for chemical assessments and research" that "continues to evolve with accessible and transparent state-of-the-art practices in literature data curation and increased interoperability to other relevant resources." EPA also <u>states</u> that "[a]II users employing ECOTOX data should consult the original scientific paper...." We mention this because potential issues with the curated datasets may occur. For example, EPA's final risk evaluation for tris(2-chloroethyl) phosphate (TCEP; CAS RN 115-96-8) includes a study published by <u>Sun *et al.* (2016)</u>. EPA <u>assigned</u> a data quality rating of "High" for this study, as part of its systematic review of the available data on TCEP. This study is also one of the curated datasets for TCEP listed in ECOTOX.

There are, however, differing scientific opinions (DSO) on the quality of Sun *et al.* (2016). During the letter peer review of the draft risk evaluation for TCEP, one of the peer reviewers <u>stated</u> that "these results [*i.e.*, Sun *et al.*, 2016] should not have been given a 'High' rating." EPA was also provided an expert review of Sun *et al.* (2016), following the public comment period on the draft risk evaluation for TCEP. The expert reviewer <u>concluded</u> that "[Sun *et al.*, 2016] does not justify a US EPA Systematic Review rating of 'High' due to a wide range of relevant and consequential weaknesses and errors and should in fact be rated 'Low'." For further discussion, see our <u>memorandum</u> dated October 2, 2024.

EPA's HAWC provides a wealth of information on EPA's public assessments. Many of these documents include study evaluation criteria that aid with understanding the strengths and limitations of the <u>cited</u> sources. Study evaluations are not, however, available on all assessments. For example, Sun *et al.* (2016) is <u>listed</u> as part of the "TSCA TCEP: Environmental and Human Health Hazard (2023)" literature review, but no study evaluation is provided.

EPA <u>states</u> in the proposed rule for the perfluorohexanesulfonic acid (PFHxS) category that there is "sufficient evidence" for listing and includes reference to EPA's draft "oral [reference dose] RfD ... of  $4 \times 10^{-10}$  mg/kg-day based on immune effects (decreased serum anti-tetanus antibody concentration in children. [citation omitted])." The proposed rule does not, however, mention concerns expressed by the Agency for Toxic Substances and Disease Registry (ATSDR) in consultation with a vaccine subject matter expert from the Centers for Disease Control and Prevention over the basis for EPA's draft oral RfD, <u>noting</u> that EPA's chosen effect level and methods used "may result in health effect values that are artificially low." EPA <u>does not</u> currently have a public assessment for PFHxS (CAS RN 355-46-4) on HAWC, so it remains to be seen whether the HAWC entry will ultimately include ATSDR's comments.

The above examples identify possible concerns with EPA relying on ECOTOX and HAWC as the

basis for supporting chemical listings on TRI. We recognize the value of these databases, but EPA must go further and evaluate the quality of studies listed in those databases rather than relying on studies simply because they are listed in ECOTOX and/or HAWC.

©2025 Bergeson & Campbell, P.C.

National Law Review, Volume XIV, Number 292

Source URL: <u>https://natlawreview.com/article/epa-proposes-add-16-pfas-and-15-pfas-categories-tri-list-chemicals</u>