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Review

A Scoping Review of PFAS Mitigation Strategies for Soil, Water, and Experimentally Exposed Fruits and Vegetables

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ABSTRACT

Per- and polyfluoroalkyl substances (PFASs) are a class of synthetic chemicals widely used in the production of industrial and consumer products. Due to their environmental persistence and health effects, PFASs have become a primary focus of global public health concern. This scoping review summarizes the literature on interventions aimed at reducing concentrations of 12 PFASs in soil and edible portions of fruit and vegetables. A comprehensive search of PubMed and Centre for Agricultural and Bioscience International (CABI) was conducted on April 9 and April 17, 2024, without date or language restrictions. Eligible references included experimental studies targeting PFAS reduction in water, agricultural soil, fruits, or vegetables. Thirty-two references, with an eligible outcome measured in soil, fruits, or vegetables, were included for data charting. Findings suggest that minimal replication exists across studies due to variability in intervention implementation, outcome measurement, and plant growing conditions. A limited number of studies evaluated soil and/or plants as outcomes of interest, with only twenty-five references providing extractable data, with most focusing on soil-based outcomes ($n = 18$) and fewer on plant-based outcomes ($n = 7$). This heterogeneity highlights a critical need for standardized methodologies to enable meaningful synthesis across the literature.

Rationale. Per- and polyfluoroalkyl substances (PFASs), a class of man-made chemicals first introduced in the 1940s, have been utilized worldwide in numerous industry and consumer products such as non-stick cookware, water-repellent clothing, stain-resistant fabrics, cosmetics, and firefighting foams (US EPA, 2024). This vast group of chemicals is valued for their stability and chemical properties that make them resistant to water and oil. The strong carbon–fluorine bonds that make PFAS useful in these types of products also make the chemicals persistent in the environment and costly to eliminate. While some longer-chain PFASs, such as perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), are no longer in production in the United States, other countries still manufacture and use them in consumer products, which are still imported. Common ways PFASs have contaminated the environment include breakdown of consumer products, wastewater streams, leachate from landfills, run-off from aqueous film-forming fire-fighting foams (AFFFs), and biosolid application (US EPA, 2024; Felizeter et al., 2021). Existing data suggest PFAS accumulate not only in soil and water but can also be taken up in a variety of food products. Previous FDA studies have found varying levels of PFAS in multiple food sources, including tuna, fish sticks, protein powder, clams, milk, and other foods (Genualdi et al., 2021; Young et al., 2022). PFASs have been found globally in the blood of both people and animals, which can build up over time with repeated exposures. The health impacts of PFAS exposure are not yet fully understood, but scientific studies have been published, and evidence exists to suggest exposure to PFAS may have different adverse health effects, including increased cholesterol levels, reduced immune response, or reduced birth weight, among others (Agency for Toxic Substances and Disease Registry (ATSDR), 2024). More research is needed to better understand the health effects of PFAS exposure. Concurrently, it is important to understand the scope of intervention studies that aim to mitigate or reduce PFAS presence in agricultural soil

Abbreviations: PFBA, perfluorobutanoate; PFBS, perfluorobutanesulfonate; PFDA, perfluorodecanoic acid; PFHpA, perfluoroheptanoate; PFHpS, perfluoroheptane sulfonic acid; PFHxA, perfluorohexanoate; PFHxS, perfluorohexanesulfonate; PFNA, perfluorononanoate; PFOA, perfluorooctanoate; PFOS, perfluorooctanesulfonate; PFPeA, perfluoropentanoate; PFPeS, perfluoropentanesulfonic acid.

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and water, as well as uptake in fruits and vegetables intended for human or animal consumption. Understanding what has been studied enables planning of research fund applications to fill knowledge gaps and avoid unnecessary duplication. If assessments of interventions have been duplicated across multiple research groups, it enables a robust assessment of the impact. However, if only one study is available for an intervention, the absence of duplicated studies across different groups limits the inference that can be drawn (Chartres & Joglekar, 2024). If one study has reported that an intervention has promise, then funding a duplicated study that confirms those findings would enable more confident policy making. Alternatively, if an intervention has been studied multiple times and the consistent impact has been measured, then it may be of little value to fund another study on the topic. Here, we use the term duplication to refer to studies conducted by different groups (across studies), rather than replicates within a study, which might be conducted within an experiment. This terminology is certainly not universal, although here it enables us to make a necessary distinction. Scoping reviews also facilitate systematic reviews that can summarize efficacy if the scoping review identifies sufficient studies for an evaluation of efficacy.

Objectives. For a topic like PFAS, the importance of understanding what has been studied and what gaps remain unexplored is essential for ensuring research efforts are directed at further exploring potentially useful avenues of research, reducing unnecessary duplication in areas that do not show promise, and identifying areas where critical gaps exist. Therefore, this article provides a summary of the literature on interventions intended to reduce 12 PFAS chemicals in water, soil, and edible portions of fruit and vegetables.

Materials and methods

Protocol and registration. Registering a protocol for scoping reviews eliminates unintended duplication of research efforts and promotes transparency (Aromataris et al., 2024). The protocol was registered with the Systematic Reviews for Animals and Food (SYREAF) on April 4, 2024 (https://syreaf.org/wp-content/uploads/2024/05/FDA-PFAS-systematic-review-protocol-April-4th-2024.pdf). Some protocol deviations were necessary as the volume of research was larger than expected. Therefore, for data characterization and extraction, we focused on interventions targeted at water, soil, or edible parts of plants. This modification was not expected to introduce a bias as the narrowly focused studies were a subset of the original search and relevance screening.

Eligibility criteria. Experimental studies conducted in water, agricultural soil, or soil that could be used for agricultural purposes, or unprocessed plant-based agricultural commodities. For example, vegetables, fruits, legumes (soybeans), pulses (peas, lentils, and beans), or grains (cereals including maize) were eligible. Plants could be grown in water, soil, amended soil, biosolids, compost, or other artificial media intended for plant growth. Agricultural water was defined as water intended or likely to contact the harvestable portion of covered produce (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety). Studies conducted in aqueous solution as a model system were also eligible. Animal products such as meat, seafood, honey, milk, and processed products were excluded.

The aim of the study must have been to reduce a detectable level of perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), perfluorononanoic acid (PFNA), or perfluorohexane sulfonic acid (PFHxS). Studies that reported the outcome as a change or difference in concentration, or a percentage reduction, were eligible. For studies that reported multiple time points, the outcome measured at the longest time point was considered most relevant. The age of the vegetable or fruit plants was irrelevant, and the outcomes for any age plant are eligible.

Eligible interventions were mutable interventions with outcomes measured in water, soil, or the edible portions of fruits and vegetables. The comparison group could include untreated, positively contaminated water, soil, or plants, or a different intervention. The comparison could also be before and after for studies assessing soil or water outcomes. Studies of nonmutable risk factors were not included; for instance, immutable factors such as differences in the concentration of PFAS in parts of the plants or differences at different growth phases of a plant were not eligible. Postharvest interventions in plants were also not eligible.

Eligible studies included experiments conducted in a population of soil or water exposed to PFAS, or plants exposed to PFAS from contaminated soil or water. The exposure to PFAS could be due to natural contamination of soil or water or spiking with PFAS by the investigator. Observational studies were not included in this scoping review.

Information sources. A literature search was conducted in PubMed and CAB Abstracts in the Michigan State University Web of Science. We also searched the bibliography of studies that passed full-text screening using a Citation chaser (https://estech.shinyapps.io/citationchaser/) and exported these references into the DistillerSR® (Evidence Partners, Ottawa, ON, Canada) review management software.

Search. The search included the concepts (1) the compound concept, (2) the matrix concept, and (3) the remediation concept. The search was based on terms used in a prior PFAS systematic review and input from collaborators. The PubMed (https://pubmed.ncbi.nlm.nih.gov) and CABI searches (using the Michigan State University Library Web of Science Interface) were conducted on April 9, 2024, and April 17, 2024, without date or language restrictions. After designing the PubMed search, we used the PolyGlot Sr accelerator to convert to a Web of Science language. The citationchaser searches were conducted on the 7th and 17th of May 2024.

Selection of sources of evidence. The search results were downloaded from each of the electronic databases in a tagged format into bibliographic software RIS files. These files were imported into DistillerSR® and de-duplicated.

Selection process. In the first round of screening, abstracts and titles were screened for inclusion based on evaluating interventions for reducing any metric of PFAS in soil, water, vegetables, fruit, legumes, pulses, or grains. Two reviewers independently evaluated 1000 citations for relevance. Thereafter, title and abstract screening was conducted with the artificial intelligence (AI) tool included in the DistillerSR® software as one reviewer and a single human reviewer serving as the second reviewer. For the AI screening tool, we used the built-in version in Distiller®. We screened from level 1 (abstract and title) to level 2 (full text evaluation). The AI tool was employed when 48 papers had been included for full-text screening. The scores for inclusion for the 48 papers were all greater than 0.90, and all the excluded papers had scores <0.65. Therefore, for the 1st "citationchaser" search (7th May), we set the AI systems to exclude citations if the score was less than 0.85, including if equal to or greater than 0.85. The system was set to require conflicts between the AI reviewer and human reviewers to be resolved. The AI reviewer conducted a review of all titles and abstracts, and each of the human reviewers was allocated roughly half of the added reviews. For the last part of the screening, when the results of the citationchaser search from May 17, 2024, were imported, we cloned the project so that we could use a sole AI review for the final ~2,000 citations. For this batch of level 1 screening, we used the AI-only setting and used scores equal to or greater than 0.90 as inclusion criteria and less than 0.90 as exclusion criteria. This point was chosen because, using the training tool with 100% screening references, the 91 included papers had scores greater than 0.90, and the scores for excluded papers were less than 0.60. A 2nd human review was not used for this last list of citations (May 17, 2024).

Full-text articles were acquired for citations passing the abstract and title screening. Two reviewers working independently evaluated the full text of each article to confirm that it met the eligibility criteria, was available in English, and the study design was experimental with natural or experimental exposure of soil or water to PFAS, or exposure of plants to PFAS via contaminated soil or water. Although the protocol defined "water" as water used or potentially used for agricultural purposes, aqueous solution was included as water for this review.

Data charting process. Data were extracted from relevant articles in two stages. Initially, descriptive data were collected on all eligible articles. This approach established the number of intervention studies available, which evaluated interventions applied to water, soil, and plants. The number was higher than expected, and a protocol deviation was necessary. The original protocol indicated that the effect of the intervention on the matrix would be conducted for all studies. However, in consultation with the research team, it was decided to focus on extracting the effect of the interventions in the soil and edible parts of plants only. Further, it was decided to focus on data extraction for 12 PFAS (Table 1) in soil or edible parts of plants. If the concentration of PFAS was reported, then these data were extracted. If concentration was not reported, then the percentage reduction of the 12 PFAS was extracted if provided. If neither concentration nor percentage reduction was reported, then data on the percent leached in soil or the edible component of a fruit or vegetable were extracted if reported. Finally, if none of these outcomes were reported, then no data extraction was undertaken.

One reviewer extracted descriptive data, while two reviewers independently extracted detailed data on outcomes measured in soil or edible components of plants. Disagreements were resolved by consensus.

Data items. The data extracted for all relevant studies included the type of soil exposed to PFAS (if applicable), whether the soil was spiked with PFAS or whether the contamination was natural, the general category of interventions evaluated, and the matrix in which the outcome was measured (soil or soil leachate, water, or plant). If the outcome was measured in one or more plants, additional data were collected on the type of plant and the part(s) of the plant that were sampled. After data extraction, the information on the general category of the intervention was categorized into the following approaches: adsorption, biological degradation, thermal degradation, photolysis, electrolysis, chemical oxidation, and others.

For the outcome data collected on soil or plants, arm-level data on a single outcome were extracted based on a hierarchy of outcome measures; if concentration with a measure of variability was reported for soil or an edible plant part, this was extracted. If concentration was not reported with a measure of variability, then the order of priority was percent removal of PFAS, concentration in soil leachate and then percent leached. The outcome for each treatment arm, plus the variability when reported, was extracted for each intervention arm for each of 12 PFAS of interest to FDA collaborators (Table 1). If multiple extraction methods were reported for the same PFAS within an article, results using methanol extraction only were extracted. If the outcome was measured over multiple time points, only results from the longest time postexposure were measured. If the authors did not report a measure of variation, we did not infer i.e. it was recorded as "not reported".

Table 1
PFAS for which data were extracted from intervention studies where the outcome was measured in soil or in an edible part of a fruit or vegetable

PFAS name	PFAS acronym
Perfluorobutanesulfonate	PFBS
Perfluorohexanesulfonate	PFHxS
Perfluoroheptane sulfonic acid	PFHpS
Perfluorooctanesulfonate	PFOS
Perfluorodecanoic acid	PFDA
Perfluorobutanoate	PFBA
Perfluoropentanoate	PFPeA
Perfluorohexanoate	PFHxA
Perfluoroheptanoate	PFHpA
Perfluorooctanoate	PFOA
Perfluorononanoate	PFNA
Perfluoropentanesulfonic acid	PFPeS

Critical appraisal of individual sources of evidence. It was originally proposed that we would assess if the studies adjusted for pseudo-replication in the statistical analysis; however, this analysis was not conducted due to the requirement for extensive data extraction of outcome results.

Synthesis of results. The results were summarized descriptively using tables. Some modifications to the PFAS data names in the extracted data were made after data extraction was completed. This was done for PFAS variables that were recorded as the salt form of the compound. In these cases, this manuscript refers to them by the more common acid form. For example, Perfluorononanoate (PFNA) is replaced with Perfluorononanoic acid (similarly, Perfluorobutanesulfonate (PFBS) was replaced with Perfluorobutanesulfonic acid (PFBS).

Results

Selection of sources of evidence. The results of the search and screening process are presented in Figure 1.

This diagram depicts the flow of information through different phases of a scoping review and maps the number of records identified, exclusion criteria, and included studies.

The search returned 6,964 citations. The 1st "citationchaser" search was conducted on 7th May, with 21 references that passed full-text screening from the PubMed and CABI search. From those 21 articles, 1,433 unique citations were identified with reference and citation searching and were imported to DistillerSR® for screening. After screening this new list of citations, we had 91 relevant articles. We then used "citationchaser" on these 91 articles and 4,060 references, of which 2,733 were unique IDs. These 2,733 were imported to DistillerSR® for screening. Throughout the search process, each time we imported a new ROS file, we used the built-in DistillerSR® deduplication process and found 1,408 duplicates.

After screening, 107 citations met the broad eligibility criteria and were included in the descriptive results (Fig. 1). Eighty-one articles assessed the effect of the intervention on water that was contaminated with a PFAS compound(s). The most common type of water was described by the authors as "aqueous solution" (Table 2). There were 11 studies where the exposure to PFAS was natural i.e. naturally contaminated water, with deliberate spiking of the water with PFAS compound(s) used in the remainder of the 70 water-focused intervention studies. There were 32 studies where soil contaminated with PFAS was the target of the intervention. The soil was naturally contaminated in 12 studies, with spiking the soil as the approach to ensuring PFAS exposure in 20 studies. A wide range of soil types was used.

Characteristics of sources of evidence. Interventions included adsorption approaches, biological degradation, thermal degradation, photolysis, electrolysis, chemical oxidation, and other approaches (Table 3). Adsorption was the approach most evaluated ($n = 48$ studies), followed by electrolysis ($n = 18$).

There were 32 studies where the outcome was measured in soil and / or plants. Seven studies did not have extractable data on soil or an edible plant part. Of the remaining 25 studies, data were extracted from tables or text for 15 studies. For the remaining 10 studies, outcome data were estimated from information provided in figures.

The number of unique studies included in the summary data was 25, including 18 studies that evaluated soil-based outcomes and 7 that evaluated plant-based outcomes. The number of PFAS tested in each

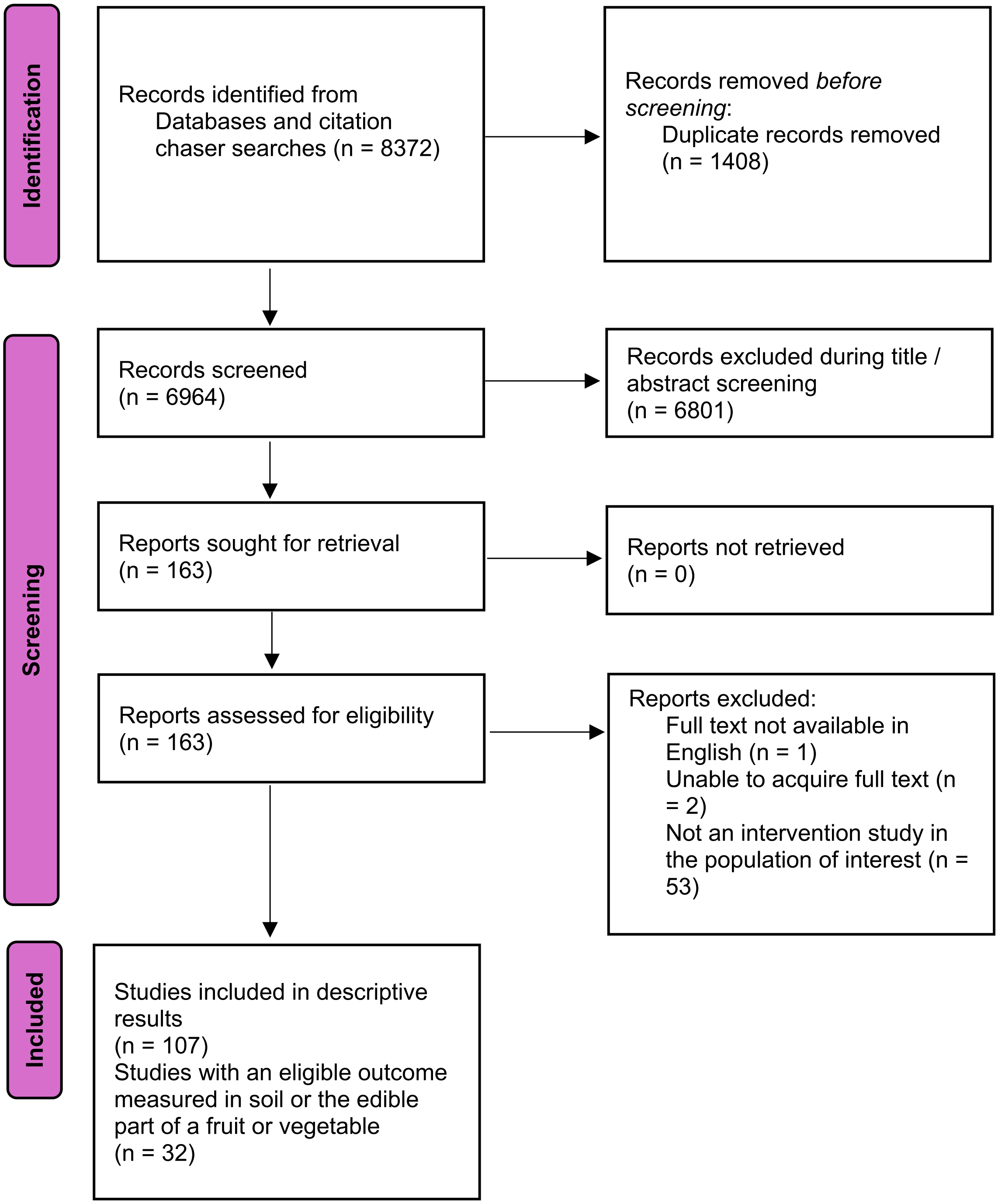

Figure 1. PRISMA flow chart illustrating the flow of citations and articles over the review process.

study ranged from 1 to 12 (the maximum number possible) (Table S3). Remaining descriptive characteristics, frequency of evaluation of each PFAS compound and frequency of measures of central tendency in pairwise comparison are described in the Supplementary Materials, respectively (Tables S4–S5).

The type of outcome measured by authors varied. Overall, the data could be organized into 941 pairwise comparisons. Each pairwise comparison comprises a unique comparison of a PFAS compound within a study with the same baseline comparison of arms. For example, if there were a study with 1 set of experimental conditions, with one single PFAS compound measured and 2 interventions, the study would have one pairwise comparison and provide 1 row of data. However, a study with 2 sets of experimental conditions (Condition X or Condition Y) that measured 2 PFAS (PFAS-A and PFAS-B) with three interventions (Intervention 1, 2, or 3) would have twelve pairwise comparisons and, therefore, twelve rows of data.

1. PFAS-A, Condition X: Intervention 1 vs Intervention 2
2. PFAS-A, Condition X: Intervention 1 vs Intervention 3
3. PFAS-A, Condition X: Intervention 2 vs Intervention 3
4. PFAS-A, Condition Y: Intervention 1 vs Intervention 2
5. PFAS-A, Condition Y: Intervention 1 vs Intervention 3
6. PFAS-A, Condition Y: Intervention 2 vs Intervention 3
7. PFAS-B, Condition X: Intervention 1 vs Intervention 2
8. PFAS-B, Condition X: Intervention 1 vs Intervention 3
9. PFAS-B, Condition X: Intervention 2 vs Intervention 3

Table 2
Descriptive results for water-related sources of exposure to PFAS

Source of exposure to PFAS	Number of articles
Contaminated water	81
Water type (as described by authors)*	
Aqueous solution	62
Ground water	14
Tap water	5
Wastewater	5
Surface water	4
Secondary effluent from wastewater treatment plant	3
Reclaimed water	1
Underground water	1
Urban stormwater detention basin	1
Water, not otherwise specified	3

* Studies may have used more than one type of water. Therefore, results sum to more than the number of studies.

10. PFAS-B, Condition Y: Intervention 1 vs Intervention 2
11. PFAS-B, Condition Y: Intervention 1 vs Intervention 3
12. PFAS-B, Condition Y: Intervention 2 vs Intervention 3

The outcomes measured were either concentration data or the percentage of change of the PFAS compound measured in the soil, the plant, or the leachate. Conducting a meta-analysis of the data requires reported measures of variation. However, only one study reported the standard error of the mean for nine pairwise comparisons. Given the diversity of intervention types, soil types, and plant growing conditions, there was little to no true duplication across research groups or studies of interventions being assessed. Here, we use the term duplication to refer to studies conducted by different groups – rather than replicates, which might be conducted within an experiment. Therefore, it was not possible to provide a meaningful synthesis of the data. The raw data are available upon request.

Discussion

Summary of evidence. Findings from this scoping review suggest that little to no duplication of the interventions investigated exists across the literature. There is substantial diversity of intervention implementation, outcome measurement, and plant growing conditions. After screening, it was clear that most articles assessed the effect of interventions on water contaminated by PFAS ($n = 81$) while a few articles assessed the effect of interventions on soil ($n = 32$). Relevant interventions included adsorption, biological degradation, thermal degradation, photolysis, electrolysis, and other interventions ($n = 22$), with adsorption being implemented most frequently across included studies. For outcome measurement, very few studies evaluated soil and/or plants as outcomes of interest, with only twenty-five references providing extractable data. Most of these studies evaluated soil-based outcomes ($n = 18$) while a few assessed plant-based outcomes ($n = 7$). Given the concern expressed about the consumption of PFAS through plants, this finding was surprising to us. Of these 7 studies, the number of PFAS evaluated per study ranged from one to twelve, with one compound representing the majority of included studies ($n = 7$). However, conducting a meta-analysis, measures of variation (standard deviation, standard error of the mean, variance, interquartile range, coefficient of variation, etc.) are required to determine the variation of change in percentage for continuous concentration data. As mentioned, only one study reported the standard error of the mean for nine pairwise comparisons, which is not consistent with quantitative summaries documented across the literature. While it was not possible to provide a meaningful synthesis of the existing data, the results do suggest that the current body of work has limited value for policy making, as few interventions have been evaluated multiple times by multiple groups. Making robust policy involves drawing broader conclusions from individual research findings by considering a collection of studies, rather than relying solely on a single study. Further, combining studies requires that variation be measured and reported, and this was very uncommon. We would propose that funding agencies and researchers should consider whether there is great value in documenting the repeatability of findings from promising prior studies of interventions or searching for new interventions.

Limitations. The authors were unable to perform a meta-analysis due to the lack of measures of variation reported in the included studies. Also, this review focused on peer-reviewed literature documented across the literature. It is unclear if the inclusion of grey literature or unpublished studies would have impacted review findings.

Conclusions

This scoping review revealed numerous data gaps linked to PFAS reporting, outcome measurement, and intervention implementation. First, there is a lack of consensus regarding the definition and classification of available PFAS, with reports varying from a few thousand to over seven million (Schymanski et al., 2023). In this review, we

Table 3
Intervention approaches used in intervention studies of PFAS in water, soil, and plants

Approach	Examples	Number of articles
Adsorption	Organic carbon, activated carbon, powdered activated carbon (PAC), granular activated carbon (GAC), RemBind, biochar, compost-amended soil, nanoparticle-activated carbons, montmorillolite, rice hulls, chitosan-based hydrogel (CEGH), fluorine and amine-functionalized porous organic polymer, membrane bioreactor (MBR) treatment, anion exchange resin, cyclodextrin (β-CD)-based polymer network, drinking water treatment residuals	48
Biological degradation	Phytoremediation, degradation by cyanobacteria	6
Thermal degradation	Heating soil to high temps	4
Photolysis	Vacuum ultraviolet (VUV) photolysis, UV/Nitrilotriacetic Acid process, TiO_2 adsorption, photodegradation, hydrogen peroxide, boron nitride(BN) for photocatalysis, tungstic heteropolyacid photocatalyst, photocatalytic ozonation, UV irradiation	12
Electrolysis	Pulsed corona discharge plasma, microbubbles, dielectric barrier discharge plasma, strip fountain dielectric barrier discharge (SF-DBD) plasma source, plasma reactors, reverse vortex gliding arc plasma (GAP), atmospheric RAdial plasma (RAP) discharge	18
Chemical oxidation	Enzyme-catalyzed oxidative humification reactions, advanced oxidation processes (AOP), gamma irradiation, heat-activated persulfate oxidation, photocatalytic ozonation, electrochemical degradation, hydrothermal oxidation, sonochemical oxidation / ultrasound	10
Other	NaNO3, full vs half time wastewater application, soil washing, use of surfactants, foam flotation process aided by metallic activators, accelerated electrons (EB), electrocoagulation, microwave-assistant catalytic membrane filtration, aeration	12

extracted twelve unique PFAS. Another significant data gap includes outcome measurement. In this review, few studies evaluated plant-based outcomes ($n = 7$), while numerous evaluated water ($n = 81$) and soil-based ($n = 32$) outcomes, indicating an undersaturation of plant-based studies across the literature.

Another critical gap includes current understandings of the uptake of PFAS in agricultural settings where food is grown for human and animal consumption. Studies have shown that PFAS uptake by plants is poorly understood and can be affected by either the size of the molecule or the permeability of the roots of the plant (Blaine et al., 2014; Blaine et al., 2013; Felizeter et al., 2021). While it seems straightforward that shorter-chain molecules exhibit greater mobility due to their smaller size, other factors such as soil makeup, pH, and availability of organic matter need to be evaluated (Adu et al., 2023; Wang et al., 2020). While several studies have documented PFAS uptake in corn, which accumulates PFAS at a higher rate in the silage, fewer studies have evaluated the uptake and transport within other edible plants (Ghisi et al., 2019; Li, Sun and Li, 2022; Wang et al., 2020; Xu et al., 2022). Coupled with studies that demonstrate the actions of precursor chemicals, the need to better understand what potential interactions between PFAS chemicals are possible, under what conditions, and where these interactions may occur (Costello & Lee, 2020). While the extant body of literature linked to the uptake of PFAS in soil and plants continues to expand, most studies are focused on a small number of PFAS and uptake is evaluated in a limited number of edible crops (Ghisi et al., 2019; Wang et al., 2020). Overall, it is critical for researchers to consider the impact of these data gaps and how they inform PFAS mitigation strategies for water, soil, and plant-based outcomes.

CRediT authorship contribution statement

Annette O'Connor: Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Elizabeth Dennard:** Project administration, Methodology, Formal analysis, Conceptualization. **Bonnie Welch:** Writing – review & editing, Writing – original draft, Investigation, Conceptualization. **Jan Sargeant:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Annette O'Connor reports that financial support was provided by the US Food and Drug Administration. Annette *O'Connor* reports a relationship with the US Food and Drug Administration that includes consulting or advisory and travel reimbursement. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. Elizabeth Dennard declares that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. Bonnie Welch declares that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. Jan M. Sargeant reports that financial support, administrative support, and travel were provided by the US Food and Drug Administration.

Appendix A. Supplementary material

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