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Environmental Notes

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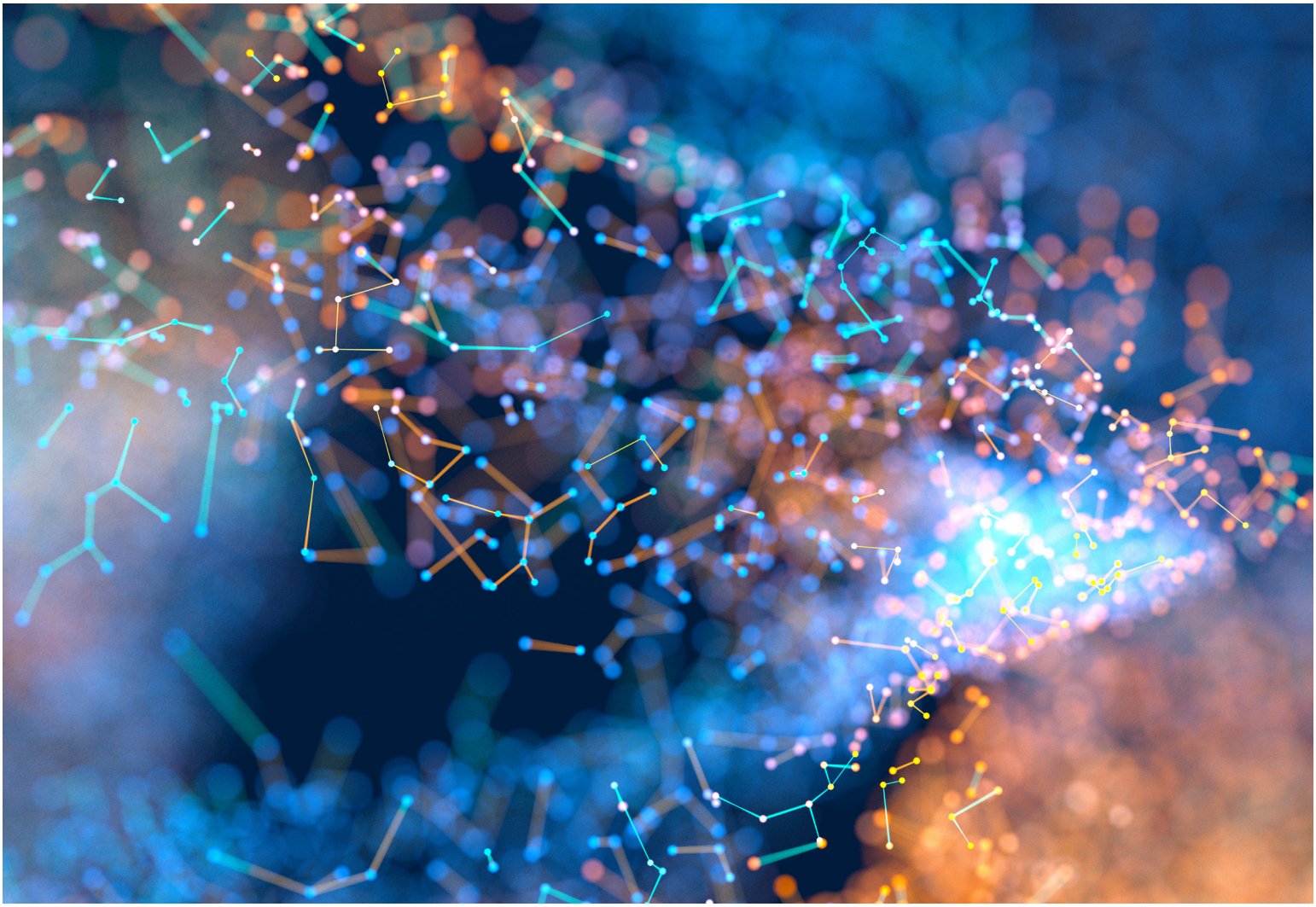

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TCE and PCE Eliminated from Most Uses

BY: ETHAN R. WARE

EPA late last year finalized rules banning use of trichloroethylene (TCE) in the United States and certain consumer uses of perchloroethylene (PCE) under the Toxic Substances Control Act (TSCA). Both chlorinated chemical solvents have been linked by EPA to cancer and are common industrial solvents. The chemicals must be phased out over the next few years.

TSCA Background

"Under TSCA section 6(a) (15 U.S.C. 2605(a)), if the Agency determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk." 89 Fed. Reg. 102571 and 103562. Consistent with this provision of TSCA, EPA has determined TCE and PCE present unreasonable risks of injury to health, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS).

TCE Phase Out

In the final regulation, EPA prohibits the manufacture and processing of TCE for most commercial and all consumer products within one year. Other uses of TCE in the workplace will gradually be eliminated over a longer period, but in the meantime strict worker safety requirements will apply. For example, permissible exposure limits will be enforced, although it is increased from what was proposed from 0.0011 to 0.2 parts per million (ppm) as part of the final regulation.

The TCE Rule applies to facilities involved in manufacture, process, distribute in commerce, use, or dispose of TCE or products containing TCE. TSCA section 3(9) defines the term "manufacture" to mean "to import into the customs territory of the United States, produce, or manufacture." Therefore, unless expressly stated otherwise, importers of TCE are subject to any provisions regulating manufacture of TCE.

According to the TCE Rule, EPA is issuing this final rule to:

1. Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for all uses (including all consumer uses);
2. Prohibit the industrial and commercial use of TCE, with longer compliance times for certain uses;
3. Prohibit the manufacture (including import) and processing of TCE as an intermediate for the manufacturing of hydrofluorocarbon 134a (HFC-134a), following an 8.5-year phase-out;
4. Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, following a 10-year phase-out;
5. Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for asphalt testing and recovery, following a 10-year phase-out;
6. Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in batch vapor degreasing for essential aerospace parts and components and narrow tubing used in medical devices, following a 7-year TSCA section 6(g) exemption;
7. Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for rocket engine cleaning by Federal agencies and their contractors, following a 7-year TSCA section 6(g) exemption;
8. Allow for limited use on vessels of the Armed Forces and their systems;

9. Prohibit the emergency industrial and commercial use of TCE in furtherance of the NASA mission for specific conditions which are critical or essential;
10. Prohibit the manufacture (including import), processing, distribution in commerce, disposal, and use of TCE as a processing aid for manufacturing battery separators for lead acid batteries, following a 20-year TSCA section 6(g) exemption;
11. Prohibit the manufacture (including import), processing, distribution in commerce, disposal, and use of TCE as a processing aid for manufacturing specialty polymeric microporous sheet materials following a 15-year TSCA section 6(g) exemption;
12. Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for essential laboratory activities and some research and development activities, following a 50-year TSCA section 6(g) exemption;
13. Require strict workplace controls to limit exposure to TCE, including compliance with a TCE workplace chemical protection program (WCPP), which would include requirements for an interim existing chemical exposure limit (ECEL) at half of the 8-hour interim ECEL, or 0.1 ppm as an 8-hour TWA;
14. Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, through a phaseout allowing for longer times for disposal necessary for certain industrial and commercial uses along with a 50-year TSCA section 6(g) exemption for disposal for cleanup projects before prohibition and interim requirements for wastewater worker protection; and
15. Establish recordkeeping and downstream notification requirements.

PCE Use Restrictions

EPA also issued a final rule aimed at addressing risks associated with the widely used PCE. According to EPA, "PCE is used for the production of fluorinated compounds, as a solvent for dry cleaning and vapor degreasing; in catalyst regeneration in petrochemical manufacturing; and in a variety of commercial and consumer applications such as adhesives, paints and coatings, aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish and wipe cleaners." 89 Fed. Reg. 103564. Like TCE manufacturers, unless expressly stated otherwise, importers of PCE are subject to provisions regulating manufacture of PCE.

To address the unreasonable risk posed by PCE, the PCE Rule:

1. Prohibits most industrial and commercial uses and the manufacture (including import), processing, and distribution in commerce of PCE for those uses;
2. Prohibits the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use;
3. Prohibits the manufacture (including import), processing, distribution in commerce, and commercial use of PCE in dry cleaning and spot cleaning through a 10-year phaseout;
4. Requires a Workplace Chemical Protection Program (WCPP), including an inhalation exposure concentration limit of 0.14 ppm (0.98 mg/m3) for inhalation exposures as an 8-hour time-weighted average (TWA), direct dermal contact controls, and related workplace exposure controls, for many occupational conditions of use of PCE not prohibited;
5. Requires prescriptive workplace controls for use of PCE in laboratories and energized electrical cleaners;
6. Establishes recordkeeping and downstream notification requirements;
7. Provides a 10-year time limited exemption under TSCA section 6(g) for certain emergency uses of PCE in furtherance of National Aeronautics and Space Administration's (NASA) mission, for specific conditions of use which are critical or essential and for which no technically and economically feasible safer alternative is available; and
8. Identifies a regulatory threshold for products containing PCE for the prohibitions and restrictions on PCE.

Conclusion

Restrictions for use and manufacture of TCE and PCE are now in force. Companies should work now to identify compliance requirements to avoid dramatic changes to production and waste management controls.

89 Fed. Reg. 102568 (Dec. 17, 2024) ("TCE Rule")
89 Fed. Reg. 103560 (Dec. 17, 2024) ("PCE Rule")

EPA Proposing to Expand Toxic Release Inventory Reporting Relating to PFAS

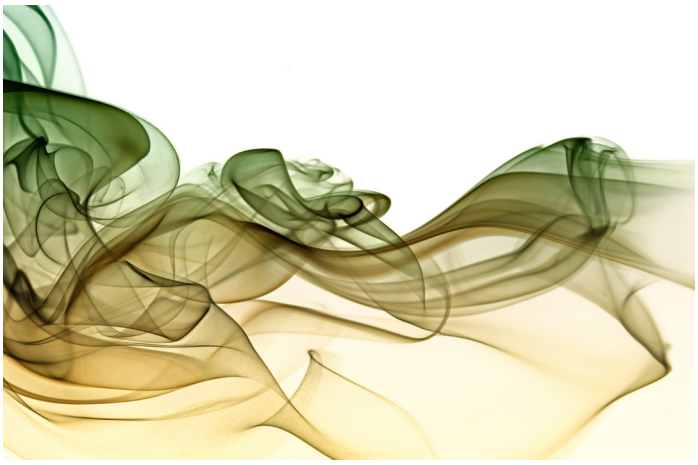
BY JESSICA J. O. KING

Since late 2019, EPA has successfully added certain perfluoroalkyl substances (PFAS) to the toxic release inventory (TRI) list of chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). On October 8, 2024, EPA published a proposed rule to add sixteen (16) additional named PFAS and fifteen (15) PFAS categories to the TRI list ("Proposed Rule"). The comment period ended December 9, 2024.

What is EPCRA TRI Reporting and why PFAS?

EPCRA requires certain manufacturers, processors, or users of listed toxic chemicals in amounts above specific reporting thresholds to annually report the amount of the applicable chemical released by the facility to the environment and how the facility manages any related chemical waste streams. To add a chemical to the TRI list, EPA must determine that the applicable 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; or
- cancer or teratogenic effects, serious or irreversible reproductive dysfunctions, neurological disorders, heritable genetic mutations, or other chronic health effects in humans; or
- a significant adverse effect on the environment of sufficient seriousness because of its toxicity, its toxicity and persistence in the environment, or its toxicity and tendency to bioaccumulate in the environment.



EPA has added numerous chemicals to the TRI list since EPCRA was first passed in 1986 and in 2020, Congress enacted the National Defense Authorization Act for Fiscal Year 2020 (NDAA FY2020) requiring TRI listing of certain PFAS if they fall under one of three categories: (1) immediate inclusion, (2) inclusion following toxicity value finalization or covered by/added to SNUR; and/or (3) EPA two-year applicability determination.

First, the NDAA FY2020 required "immediate inclusion" in the TRI inventory the following PFAS with a reporting threshold of 100 pounds: (1) perfluorooctanoic acid (PFOA) and related salts, (2) perfluorooctane sulfonic acid (PFOS) and related salts, (3) any PFAS substance or class of PFAS substances listed as an active chemical substance in the 2019 Toxic Substances Control Action inventory and already regulated under the significant new use regulations (SNUR), (4) hexafluoropropylene oxide dimer acid (GenX), (5) perfluorononanoic acid (PFNA), and (6) perfluorohexanesulfonic acid (PFHxS).

Secondly, the NDAA FY2020 allowed "inclusion following assessment" of any PFAS for which EPA finalizes a toxicity value or for which EPA determines it is covered by or added to the SNUR.

Lastly, the NDAA FY2020 requires EPA to:

- Within two years, determine for TRI listing any PFAS not specifically listed for "immediate inclusion" above, **including** a list of thirteen (13) specific listed PFAS and two (2) PFAS categories (PFAS for which EPA has validated a drinking water test method and PFAS used to manufacture fluorinated polymers); and
- Within two years of the determination described above, revise the TRI to add the applicable chemicals.

What Chemicals and Categories is EPA proposing to Add and Why?

The proposed rule applies only to those PFAS for which EPA finalized a toxicity value or otherwise made a positive two-year applicability determination. It does not add those PFAS or PFAS categories added automatically on January 1 of each year as covered by a SNUR.

In the proposed rule, EPA determined that there are thirty-nine (39) PFAS chemicals that Congress directly asked EPA to consider for listing. Of those 39, EPA determined thirteen (13) had already been added by Congress, seventeen (17) are not yet ready to be proposed for listing based on available data, and nine (9) are ready for listing. EPA also added seven (7) additional PFAS and fifteen (15) PFAS categories because it interpreted Congress' use of the word "including" in the Act as an open invitation to add any that meet the EPCRA TRI applicability criteria.

Finally, EPA concluded that the PFAS proposed for addition can either reasonably be anticipated to cause adverse chronic human health effects at moderately low to low exposure doses and/or environmental effects at low concentrations or have moderately high to high human health toxicity and/or are highly toxic to aquatic organisms. EPA did not perform exposure considerations for those PFAS considered for listing due to chronic health effects or effects on the environment as EPA believes EPCRA only requires exposure assessments for those proposed for listing due to acute human health effects. None of the proposed PFAS or PFAS categories in the proposed rule are being listed for a finding of acute human health effects.

The proposed list includes the following:

16 PFAS:

1. Broflanilide;
2. 1-Butanesulfonamide,1,1,2,2,3,3,4,4,4-nonafluoro-N-methyl- (MeFBSA)
3. 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-nonafluoro-N-(2-hydroxyethyl)-N-methyl- (MeFBSE)
4. Cyclopentene, 1,3,3,4,4,5,5-heptafluoro- (HFCPE)
5. Ethanesulfonamide, 1,1,2,2,2-pentafluoro-N-[(pentafluoroethyl) sulfonyl]-, lithium salt;
6. 6:2 Fluorotelomer alcohol (6:2 FTOH))
7. Fulvestrant (CASRN 129453-61-8)
8. Hexaflumuron
9. Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)
10. Perfluorotridecanoic acid (PFTrDA)
11. 2-Propenoic acid, 2[methyl [(nonafluorobutyl) sulfonyl]amino]ethyl ester (MeFBSEA)
12. Pyrifluquinazon
13. Tetraconazole
14. Triethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tri-deca-fluorooctyl)silane
15. Trifluoro(trifluoromethyl) oxirane (HFPO)
16. Perfluoro(2-ethoxy-2-fluroethoxy)acetic acid ammonium salt (Chemical Abstracts Service No. 908020–52–0)

15 PFAS Categories:

1. 9-Chlorohexadecafluoro-3-oxanone-1-sulfonic acid (9Cl-PF3ONS), Salts, and Sulfonyl Halides Category;
2. 11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid (11Cl-Pf3OUdS);
3. Hexafluoropropylene oxide dimer acid (HFPO-DA, GenX), Salts, and Acyl Halides Category;
4. Perfluorobutanesulfonic acid (PFBS), Salts, Sulfonyl Halides, and Anhydride Category;
5. Perfluorobutanoic acid (PFBA), Salts, Acyl Halides, and Anhydride Category;
6. Perfluorodecanoic acid (PFDA), Salts, Acyl Halides, and Anhydride Category;
7. Perfluorododecanoic acid (PFDoA), Salts, Acyl Halides, and Anhydride Category;
8. Perfluorohexanesulfonic acid (PFHxS), Salts, Sulfonyl Halides, and Anhydride Category;
9. Perfluorohexanoic acid (PFHxA), Salts, Acyl Halides, and Anhydride Category;
10. Perfluorononanoic acid (PFNA), Salts, Acyl Halides, and Anhydride Category;
11. 1H,1 H, 2 H, 2 H-Perfluorooctane sulfonic acid (6:2 FTS), Salts, and Sulfonyl Halides Category;
12. Perfluorooctanoic acid (PFOA), Salts, Acyl Halides, and Anhydride Category;
13. Perfluorooctanesulfonic acid (PFOS), Salts, Sulfonyl Halides, and Anhydride Category;
14. Perfluoropropanoic acid (PFPrA), Salts, Acyl Halides, and Anhydride Category; and
15. Perfluoroundecanoic acid (PFUnA), Salts, Acyl Halides, and Anhydride Category.

Who will be affected by the proposed rule?

EPA estimates the proposed rule, if adopted, will result in an additional 356 to 1,110 TRI reporting forms filed annually by affected facilities. Any facility that manufactures, processes, or uses any of the PFAS of PFAS categories listed in this rule may be affected.

What does this mean to me?

EPA requested comments on the rule. Some of the types of comments EPA requested include:

- The appropriateness of the definition of PFAS EPA applied to this rule;
- The appropriateness of EPA's use of certain

databases (such as ECOTOX and EPA HAWC) as "final" toxicity determinations for the purpose of this rule;
- What is required of EPA to determine if a chemical has chronic health effects or significant adverse effects of the environment;
- How EPA came up with categories verses specific chemical listings and whether those categories are appropriate and/or should be expanded;
- Whether it is appropriate for EPA to require reporting for the aggregate weights of releases from all constituents in a category or to report the weights of just the parent;
- Whether EPA has missed any PFAS that it should have included; and
- Whether the 100-pound threshold is appropriate for this listing and future PFAS listing thresholds.

If you are potentially affected by this proposed rule or believe you will be affected by future proposed rules adding additional PFAS of PFAS categories to the TRI List, you should continue to monitor this rulemaking and any additional regulatory actions that may be undertaken by EPA.

89 Fed. Reg. 81776 (October 8, 2024)
EPA Docket No.: EPA-HQ-OPPT-2023-0538
40 CFR Part 372

Dust Off Your Rulebook: EPA's New Dust-Lead Standards

BY: WILLIAM D. "BILL" KURIGER

EPA has published a Final Rule which will lower dust-lead standards in pre-1978 homes and childcare facilities. Under TSCA Section 403, EPA must identify and regulate lead-based paint hazards. The Final Rule and its regulatory predecessors identify lead-based paint hazards which in turn determine applicability of the Lead-Based Paint Disclosure Rule ("Disclosure Rule") and the Lead Renovation, Repair, and Painting Rule ("RRP Rule"). Prior to the Final Rule, EPA used near-identical standards to (1) identify a threshold dust-lead concentration which establishes a "lead-based paint hazard" and (2) determine whether EPA recommends abatement action. The Final Rule establishes two unique standards to guide these determinations. Sellers and lessors of pre-1978 homes and firms which conduct lead-based paint activities, operate lead-based paint training programs, or are certified to conduct lead-based paint activities or renovations are affected by the new standards of the Final Rule.

EPA regulations do not compel property owners to take abatement actions, but rather set standards to identify lead-based paint hazards (for which EPA recommends abatement actions) and determine whether abatement is complete. Prior to this Final Rule, all affected persons would be subject to dust-lead hazard standards of 10 and 100 µg/ft2 for floors and window sills, respectively; post-abatement, an additional standard of 400 µg/ft2 applied to troughs. The Final Rule provides a standard for identifying a lead-based paint hazard in regulated housing, as well as a distinct standard for whether further action is recommended post-abatement.

Regardless of abatement status, affected persons must test for consistency with the "dust-lead hazard standard" ("Hazard Standard") in risk assessments and lead hazard screens. Concentrations above the Hazard Standard indicate a lead-based paint hazard which triggers requirements under the Disclosure and RRP Rules. The Final Rule redefines the Hazard Standard as the "dust-lead reportable level" ("Reportable Level"). Accordingly, the new Reportable Level is "any reportable level as analyzed by a laboratory recognized by EPA's National Lead Laboratory Accreditation Program (NLLAP)." The "reportable level" for a laboratory is the lowest level at which the laboratory can reliably report results. In effect, any reliably detectable level of dust-lead exceeds the Reportable Level and therefore constitutes a lead-based paint hazard.

After (and if) abatement is performed, target housing must meet the "post-abatement dust-lead clearance level" ("Clearance Level"). The Clearance Level is used to determine whether EPA recommends further abatement action and whether abatement work performed can be considered complete. The Final Rule redefines the Clearance Level as the "dust-lead action level" ("Action Level"). The Final Rule sets the Action Levels as follows:

- Floors: 5 µg/ft2
- Window Sills: 40 µg/ft2
- Troughs: 100 µg/ft2

Historically, the program recommended action when dust-lead loadings are at or above the Hazard Standards (those being effectively the same as the Clearance Levels); the Final Rule now recommends action when dust-loadings are at or above the Action Levels. When dust-loadings are above the Reportable Levels, but

below the Action Levels, EPA recommends only best practices, such as a HEPA vacuum and regular cleaning, rather than abatement.

In recognition of scenarios where target housing is abated below the Action Levels but not the Reportable Levels, EPA is amending the requirements for abatement reports. Certified firms conducting abatement activities must include in their abatement reports specific language from the regulation directing the reader to a reference document titled "*Protect Your Family From Lead in Your Home*," which clarifies lead-based paint hazards may remain after abatement. Affected persons must consider that successful abatement does not necessarily mean there is no remaining lead-based paint hazard for purposes of Disclosure or RRP Rule compliance.

EPA has set a compliance date for the Final Rule of January 12, 2026. Affected persons should plan to begin adapting to the new scheme of Reportable Levels and Action Levels so to avoid noncompliance once the Final Rule takes effect.

89 Fed. Reg. 89416 (November 12, 2024)

D.C. Circuit Court of Appeals Vacates the Confidential Business Rule under TSCA

BY: TANNER N. BRANTLEY

The D.C. Circuit Court of Appeals vacated a portion of the Confidential Business Information rule (CBI) in the Toxic Substances Control Act (TSCA) regulations as the panel of judges found it unlawfully allows for the unwanted disclosure of chemical manufacturers' trade secrets.

TSCA Overview

TSCA was established by Congress to prevent unreasonable risks of injury to health and the environment from manufacture, processing, distribution in commerce, use and disposal of chemical substances and mixtures. Through TSCA, EPA is authorized to require reporting, record-keeping, and testing, and to impose restrictions relating to chemical substances and mixtures. Any party that intends to manufacture a chemical substance which is not yet on the TSCA Chemical Substance Inventory (CSI) must submit the required notice of such to EPA. EPA maintains two sections of the CSI in order to protect confidentiality while also facilitating the public knowledge of which chemical substances are already in commerce in the United States. The non-confidential section includes non-confidential chemical substances identified in part by their specific chemical identities and the confidential section includes public identifiers, such as accession numbers, for chemical substances whose identities are claimed as confidential. The confidential portion of the CSI is not available to the public and includes the specific chemical identities of chemical substances claimed as confidential.

Confidential Business Information Rule

On June 7, 2023, EPA issued the final CBI rule. The CBI Rule concerns the assertion and treatment of confidential business information claims for information reported to or otherwise obtained by EPA under TSCA. Any entity submitting information to EPA under TSCA may claim that certain information is confidential business information, so long as it is permitted by the

applicable regulations and TSCA section 2613. Generally, CBI claims must be substantiated and routinely reviewed by EPA. Additionally, CBI claims for chemical identities made prior to commercialization are not to be subject to such substantiation or review. The Rule exempts pre-commercialization CBI claims from substantiation and review until a post-commercialization claim is filed. The court found this consistent with the TSCA's provisions. As clarified by the Court of Appeals, Section 2613(c)(2) mandates that a CBI claim for information as outlined in subsections (A) through (G) shall not be subject to substantiation requirements and are not subject to durational limits to the exemption based upon a discrete period. The Court noted the "prior to" language is only present in subsection (G) and modifies the category of CBI that is exempt from substantiation. The Court held that while there is not a durational limit on the CBI exemption, it is not unconditional and could be waived.

Waiver of the Confidential Business Information Rule

The three-judge panel held that the CBI Rule under the regulations would allow downstream customers, such as processors or importers, that only know of a substance's chemical name and non-confidential accession number to inadvertently waive confidentiality by submitting a report to the EPA that identifies the substance by its non-confidential referents. Even though the existing regulatory regime requires the downstream users of a chemical substance to submit such a report to EPA, the downstream user may not possess any confidential information regarding the chemical, and therefore would be unable to effectively assert or substantiate a CBI claim. The downstream customer, despite lacking the necessary confidential information, are required to assert and substantiate a CBI claim, even though the report they submit is likely to only contain non-confidential information regarding the chemical. Thus, although the downstream customer does not have the required information necessary to support such a claim, they are afforded no exception to this CBI assertion or substantiation requirement and the EPA may deem the CBI claim waived.

The Court was also concerned with the potential waiver of a competitor's CBI claim and stated the rule "would allow downstream entities without knowledge to inadvertently or intentionally waive a competitor's CBI claim." Although the EPA has acknowledged this issue and stated it would be better addressed in later rules, the Court held that the current CBI Rule allows for unauthorized disclosures of confidential information and that EPA cannot wait to address the unlawful disclosures that are contrary to law.

Conclusion

The Court of Appeals concluded the CBI Rule is unlawful to the extent it allows a downstream entity reporting on a chemical substance by accession number and without knowledge of the underlying specific chemical identity to waive confidentiality for that specific chemical identity. Note the Court only vacated those specific requirements of the CBI Rule. It is likely that EPA will propose a revised CBI Rule within the year. Entities that utilize chemicals that are subject to TSCA reporting requirements and may be subject to the CBI Rule should stay abreast of any potential regulatory changes.

Environmental Defense Fund v. United States Environmental Protection Agency,
No. 23-1166, 2024 WL 5176219 (D.C. Cir. Dec. 20, 2024)

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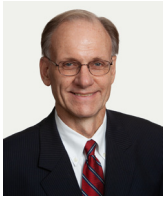

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