ORAL ARGUMENT NOT YET SCHEDULED

Docket No. 24-1151
Consolidated with Docket Nos. 24-1185, 24-1182, 24-1202, 24-1237

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEXAS CHEMISTRY COUNCIL, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

OLIN CORPORATION, et al.

Intervenors.

On Petition for Review of Final Action by the
U.S. Environmental Protection Agency

JOINT OPENING BRIEF OF PETITIONERS TEXAS CHEMISTRY COUNCIL, AMERICAN CHEMISTRY COUNCIL, AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS, AND AMERICAN PETROLEUM INSTITUTE

Rafe Petersen
Meaghan Colligan
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

Attorneys for Petitioners, Texas Chemistry Council and American Chemistry Council

David Y. Chung
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
Tel.: (202) 624-2567

Attorney for Petitioners, American Fuel & Petrochemical Manufacturers and American Petroleum Institute

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), counsel for Texas Chemistry Council, American Chemistry Council, American Fuel & Petrochemical Manufacturers, and American Petroleum Institute certify as follows:

(A) Parties and Amici.

Petitioners: The Petitioners to this case are American Chemistry Council; Texas Chemistry Council; American Fuel & Petrochemical Manufacturers; American Petroleum Institute ("**Petitioners**") and United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO; International Association of Machinists and Aerospace Workers; Worksafe, Inc. ("**Labor Petitioners**").

Respondents: The Respondents to this case are the United States Environmental Protection Agency and Administrator Michael Regan.

Petitioner-Intervenors: The Petitioner-Intervenor to this case is Olin Corporation.

Respondent-Intervenors: The Respondent-Intervenors to this case are Sierra Club and Alaska Community Action on Toxics.

(B) Rulings Under Review. The Petition for Review challenges the U.S. Environmental Protection Agency's final agency action titled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act", which appears

in the Federal Register at 89 Fed. Reg. 37,028 (May 3, 2024) (the "**Rule**"). The Rule is codified at 40 C.F.R. Part 702, Subpart B.

(C) Related Cases.

Each of the petitions for review consolidated with Case No. 24-1185 is related. These cases consist of the following, none of which has been previously reviewed by this or any other Court:

- *United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union v. U.S. Environmental Protection Agency*, Case No. 24-1151
- *International Association of Machinists and Aerospace Workers v. U.S. Environmental Protection Agency,* Case No. 24-1182
- *Worksafe, Inc. v. U.S. Environmental Protection Agency,* Case No. 24-1202
- *American Fuel & Petrochemical Manufacturers and American Petroleum Institute v. U.S. Environmental Protection Agency*, Case No. 24-1237

CORPORATE DISCLOSURE STATEMENT

Under Federal Rule of Appellate Procedure and D.C. Circuit Rule 26.1, Petitioners hereby provide the following disclosures:

American Chemistry Council ("**ACC**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. ACC is a "trade association" under Circuit Rule 26.1.

Texas Chemistry Council ("**TCC**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. TCC is a "trade association" under Circuit Rule 26.1.

American Fuel & Petrochemical Manufacturers ("**AFPM**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. AFPM is a "trade association" under Circuit Rule 26.1.

American Petroleum Institute ("**API**") states that it has no parent corporation and does not issue stock to the public, and thus no publicly held corporation owns 10% or more of its stock. API is a "trade association" under Circuit Rule 26.1.

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GLOSSARY OF ABBREVIATIONS

ACC	American Chemistry Council
AFPM	American Fuel & Petrochemical Manufacturers
APA	Administrative Procedure Act
API	American Petroleum Institute
ECEL	Existing Chemical Exposure Limit
EPA	United States Environmental Protection Agency
OSHA	Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act
PEL	Permissible Exposure Limit
PPE	Personal Protective Equipment
TCC	Texas Chemistry Council
TSCA	Toxic Substances Control Act

INTRODUCTION

Chemicals serve as the building blocks for every aspect of our daily lives – from the clothes we wear, to the products we consume, and the equipment we utilize to help keep us safe. In 1976, Congress enacted the Toxic Substances Control Act ("**TSCA**") authorizing the U.S. Environmental Protection Agency ("**EPA**") to identify risks posed by chemicals to human health and the environment. Congress intended TSCA to *supplement* other statutes and regulations, not subsume them.

Petitioners are trade associations whose member companies manufacture, process, distribute, sell, and use chemicals. As such, Petitioners are regulated by TSCA and support chemical regulation that is comprehensive, reasonable, based on current science, and consistent with Congressional intent.

In 2016, Congress amended TSCA ("**2016 Amendments**") to establish a process for EPA to evaluate the risks of existing chemicals. EPA is required to first prioritize certain existing chemicals as "high priority" ("**Prioritization**"). Then, EPA is required to evaluate the risks associated with certain uses of those high priority chemicals ("**Risk Evaluation**"), and issue a determination as to whether there is an unreasonable risk from any of the identified uses ("**Risk Determination**").[1] Following the Risk Determination, TSCA directs EPA to

[1] Collectively, the Risk Evaluation and Risk Determination stages are referred to herein as the "**Risk Evaluation Process**".

implement regulations, to the extent necessary, to address unreasonable risks identified for specific uses during the Risk Evaluation Process ("**Risk Management**"). The 2016 Amendments required the agency to promulgate procedural regulations to describe how chemicals would undergo Risk Evaluation. These regulations were published in 2017 ("**2017 Rule**"). *See* "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act," 82 Fed. Reg. 33,726 (July 20, 2017).

EPA's 2017 Rule was consistent with the plain language of TSCA. EPA recognized that TSCA instructs the agency to complete Risk Evaluations by focusing on the specific conditions of use of a chemical, and issuing separate Risk Determinations for each of the relevant uses ("**Use-By-Use Approach**"). In determining which uses to assess in the Risk Evaluation, EPA's 2017 Rule indicated it would evaluate the uses that raise the greatest potential for risk so it would have the capacity to comply with statutory deadlines. Put differently, the 2017 Rule required EPA to identify the specific uses[2] for each chemical EPA sought to evaluate, concentrating on categories of uses of the chemical throughout key lifecycle stages such as manufacturing, processing, distribution, and disposal.[3]

[2] TSCA defines and refers to these specific uses of chemicals as the "conditions of use", which is used interchangeably with "use" herein. 15 U.S.C. § 2602(4).
[3] In the Risk Evaluation Process, these categories of uses are broken down into the more specific conditions of use. For example, in the Risk Evaluation for methylene

In May 2024, EPA upended the Risk Evaluation Process with the rule challenged here. *See* Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 89 Fed. Reg. 37,028 (May 3, 2024) ("**Rule**"). In two critical ways, the Rule completely reversed EPA's prior interpretation of TSCA's directive to complete its Risk Evaluation Process by focusing on conditions of use. First, rather than focusing on uses with the greatest exposure potential, which is required by the plain language of TSCA, EPA has now erroneously concluded that TSCA requires review of *every possible use* of a chemical in its Risk Evaluations ("**All Conditions of Use Approach**"). Second, EPA reversed it prior position on Risk Determinations – now stating that Congress requires Risk Determinations based on the chemical as a whole, in every instance, without flexibility ("**Whole Chemical Approach**"). This is a novel and non-scientific approach to risk assessment; it is not a regulatory approach designed to accurately address risks from the potential exposures associated with each specific condition of use, which is the Congressional intent of TSCA. Congress intended for EPA to have the flexibility to determine

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chloride, EPA evaluated 53 conditions of use within these categories, including: manufacturing (import); processing (repackaging, recycling, incorporation into a formula or mixture); industrial and commercial use as a laboratory chemical; plastic and rubber products manufacturing; and bonding agents for solvent welding. Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 67,901, 67,905-06 (Nov. 10, 2022).

which conditions of use should be evaluated based on potential for risk, and issue individual Risk Determinations for each use evaluated.

These new approaches necessitate industry to provide data to EPA – at exorbitant expense – to inform the agency about all uses prior to the Risk Evaluation, and to comment on expanded exposure assessments, even when those exposures are unlikely to occur or contribute significantly to overall risk or are related to a use that industry does not intend to pursue. By disregarding its duty to differentiate between the vastly distinct ways that chemicals are used, e.g. for use in a laboratory vs. in children's toys, EPA improperly tilts the scale toward finding unreasonable risk. This has already resulted in unreasonable Risk Determinations for every Risk Evaluation that EPA has conducted under the Whole Chemical Approach. It is difficult to imagine that EPA would find that *any* chemical does not pose unreasonable risk when evaluated as a whole substance, rather than by conditions of use.

Further, TSCA's directives for EPA to evaluate "all available information" related to "the likely duration, intensity, frequency and number of exposures under the condition of use of the chemical substance," surely includes well-established Occupational Safety and Health Administration ("**OSHA**") regulations requiring the use of personal protective equipment ("**PPE**") when considering chemical exposures to workers. But EPA's failure to account for compliance with existing regulatory

PPE requirements ("**No-PPE Assumption**") leads to faulty conclusions on chemical exposure and usurps other agencies' authorities. EPA must analyze the actual level of exposure to workers, which is not possible without evaluating how those exposures and any risks have already been mitigated by OSHA's relevant mandates for use of PPE and other worker protection measures.

Petitioners challenge the Rule as contrary to the plain language of TSCA and Congress's intent in adopting the 2016 Amendments to create a focused, systematic, and science-based Risk Evaluation Process, that allows EPA the flexibility to determine the conditions of use of a chemical that should be evaluated based on potential for risk. The Rule creates a wholly impracticable Risk Evaluation Process that wastes significant resources by requiring detailed review of every hypothetical circumstance in which a chemical has ever been or could be created, used or disposed of, resulting in the unreasonable, onerous, unnecessary and duplicative regulation of chemicals, without any flexibility. The Rule is arbitrary, capricious, not in accordance with law and should be set aside.

STATEMENT OF JURISDICTION

Respondents EPA and Administrator Michael S. Regan ("**Respondents**") issued the Rule pursuant to their authority under TSCA. 15 U.S.C. §§ 2605(b)(1)(A), (4)(B). The U.S. Courts of Appeals have jurisdiction to review final agency rules issued under TSCA. *Id*. § 2618(a)(1)(B). Venue is proper in this Court because

Petitioners ACC's, AFPM's, and API's principal places of business are in the District of Columbia.

The Rule was published on May 3, 2024, *see* 89 Fed. Reg. 37,028, and issued for purposes of judicial review on May 17, 2024. *See* 40 C.F.R. § 23.5(a); 15 U.S.C. § 2618(a)(2) (citing 28 U.S.C. § 2112). Petitioners ACC and TCC filed a timely petition for review in the Fifth Circuit Court of Appeals on May 24, 2024. Other Petitioners filed timely petitions for review challenging the Rule in the Fourth, Ninth, and D.C. Circuits. The Judicial Panel on Multidistrict Litigation selected this Court for the consolidation of all the petitions via Consolidation Order dated June 5, 2024. All petitions challenging the Rule were subsequently consolidated in this Court via orders dated June 7, 2024, June 17, 2024, and August 9, 2024.

STATUTES, RULES, AND REGULATIONS

The pertinent statutes and regulations are provided in the Addendum.

STATEMENT OF THE ISSUES

I. Whether the All Conditions of Use Approach is arbitrary, capricious, and not in accordance with law because it disregards the plain language and intent of TSCA, which requires the Administrator to determine which conditions of use raise the greatest potential for risk and should be evaluated.

II. Whether the Whole Chemical Approach is arbitrary, capricious, and not in accordance with law because it disregards TSCA's concept of "conditions of use"

which requires that EPA issue Risk Determinations for the specific uses of a chemical.

III. Whether EPA violated constitutional due process protections by failing to provide ascertainable certainty and clarity to the regulated community regarding the scope of future EPA chemical regulation as a result of the Whole Chemical Approach.

IV. Whether the No-PPE Assumption exceeds EPA's authority by disregarding the use of PPE by workers, even if required under worker protection laws, when evaluating chemical exposures.

STATEMENT OF THE CASE

In response to the growing use of industrial chemicals, Congress enacted TSCA in 1976. As Congress emphasized when it amended TSCA in 2016, the Act's purpose is to "fill a number of regulatory gaps" that existed in the regulation of chemicals that were widely sold, distributed, and utilized in manufacturing operations and industrial, commercial, and consumer products. *See* H.R. Rep. No. 144-76, at 28 (2015).

Section 6 of TSCA was amended to establish a review process for existing chemicals, which requires EPA to: (1) prioritize certain existing chemicals as "high

priority" or "low priority" ("**Prioritization**");[4] and (2) identify and assess hazards and exposures associated with certain uses of those designated high priority chemicals ("**Risk Evaluation**"), and issue a determination as to whether there is an unreasonable risk from any of the identified uses ("**Risk Determination**").

For chemicals designated as "high priority," EPA must conduct "risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation . . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). The "scope" of the Risk Evaluation must include "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider . . . ." *Id*. § 2605(b)(4)(D).

Each Risk Evaluation will include a tiered and targeted examination of potential hazards and exposures of a chemical under the "conditions of use" based on the best available science, while integrating hazard and exposure assessments, and considering uncertainty and variability, data quality, and environmental risks. *Id*. §§ (F)(i); 2625(h), (i). Then, based on the "best available science" and "weight

[4] Prioritization requires EPA to determine if an existing chemical substance is a high or low priority for risk evaluation. 15 U.S.C. § 2605(b)(1)(A). This requires "consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances . . . the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed." *Id.*

of the scientific evidence," EPA must issue a Risk Determination of whether the uses of the chemical identified by the Administrator pose unreasonable risk. *Id.* § 2605(b)(4)(A).

If, after the Risk Evaluation, EPA finds "no unreasonable risk" for each use reviewed, the Risk Evaluation Process ends. If, however, EPA finds "unreasonable risk" for one, some, or all of the uses reviewed, then EPA must move to Risk Management, which requires EPA to promulgate regulations within two years addressing the risks associated with *specific* uses of the chemical to the extent necessary so that the chemical no longer presents an unreasonable risk. *Id*. § (a) (emphasis added).

The 2016 Amendments required EPA to promulgate rules implementing the Risk Evaluation Process, which EPA did in 2017. *See* 82 Fed. Reg. 33,726. Under the 2017 Rule, EPA interpreted TSCA to require the agency to (1) select *which* chemicals to evaluate and under *what* conditions of use and (2) make final Risk Determinations on those conditions of use. Specifically, EPA concluded that it had "discretion to determine the conditions of use that [it] will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk." *See* 82 Fed. Reg. 33,726 (*citing* 162 Cong Rec, S3519-S3520 (2016)). EPA further concluded that, identifying the "circumstances" that constitute a "condition of use" of each chemical

substance will "inevitably involve the exercise of some discretion . . . consistent with the objective of conducting a technically sound, manageable evaluation." *Id.* Finally, EPA vowed to "make individual risk determinations for all uses identified in the scope." *Id.*

In 2024, EPA abandoned this correct approach of concentrating on conditions of use with the greatest potential for exposure, as codified by Congress in TSCA. Under the Rule challenged here, EPA misinterprets the statutory requirements, now insisting that Congress commanded the agency to consider all conceivable scenarios, even those that are unlikely to occur or that present little potential for risk. 89 Fed. Reg. 37,035. There are no such provisions in the underlying statutory language. In fact, TSCA acknowledges the use of "sentinel exposures" (*i.e.*, focusing on conditions of use that contribute the greatest potential exposures) in 15 U.S.C. § 2605(b)(4)(F)(ii). EPA cites to several authorities in support of its changed interpretation, none of which bolster EPA's unauthorized, capacious expansion of the Risk Evaluation Process, including adopting the All Conditions of Use Approach, Whole Chemical Approach, and No-PPE Assumption. 89 Fed. Reg. 37,031, 37,035, 37,037.

SUMMARY OF THE ARGUMENT

Petitioners respectfully request that this Court grant the petitions for review and set aside the Rule for three principal reasons.

First, EPA's All Conditions of Use Approach is contrary to TSCA, which requires the Administrator to focus on those particular uses of a chemical that have the greatest potential for exposure in order to ensure a timely, thorough, and science-based review process. Additionally, the All Conditions of Use Approach impermissibly renders several provisions of TSCA inoperative and superfluous, including those related to scoping and federal preemption. Finally, the inherent structure of TSCA, including strict statutory deadlines, mandates that the Administrator prioritize uses for Risk Evaluation.

Second, EPA's Whole Chemical Approach for Risk Determinations is contrary to TSCA, which commands the agency to evaluate chemicals and issue Risk Determinations based on the "conditions of use" identified by the Administrator, and only regulate through Risk Management those uses of the chemical that are deemed to pose an unreasonable risk.

The Whole Chemical Approach will result in unreasonable Risk Determinations being driven by one singular use that poses an unreasonable risk, even if all other uses do not, as well as duplicative regulation of uses that are thoroughly regulated by existing federal frameworks. Finally, the Whole Chemical Approach violates due process protections because the regulated community will lack ascertainable certainty regarding which uses actually present an unreasonable risk.

Third, the Rule's No-PPE Assumption is contrary to TSCA's requirement that EPA "integrate and assess" all "available information on hazards and exposures" when conducting Risk Evaluations. Failing to account for the use of PPE also contravenes the statutory definition of "conditions of use" because speculative misuse/non-use of PPE and willful violations of other laws is not "intended, known, or reasonably foreseen" by EPA.

Further, automatically excluding the use of required PPE in an exposure assessment does not conform to the "best available science" provisions in 15 U.S.C. § 2625(h) because this assumption distorts the actual exposure potential. Risk Evaluations conducted with the No-PPE Assumption incorrectly and consistently assume a higher level of exposure than calculations considering existing OSHA PPE requirements, resulting in arbitrary Risk Determinations for every chemical for which EPA evaluates risks to workers.

STATEMENT OF STANDING

Petitioners have associational standing because: (1) their members have standing in their own right; (2) the interests they seek to protect are germane to their purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977).

Petitioners satisfy the first *Hunt* factor because their members are directly regulated by the challenged Rule. *See Twin Rivers Paper Co. LLC v. SEC*, 934 F.3d 607, 614 (D.C. Cir. 2019); 89 Fed. Reg. 37,028 (listing potentially affected entities who "are required to follow" the "process and requirements" in the Rule). In cases like this, when objects of governmental regulation "challeng[e] the legality of government action or inaction . . . , there is ordinarily little question that the action or inaction has caused [them] injury, and that a judgment preventing or requiring the action will redress it." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992).

To be clear, there is a "substantial probability" that multiple members will suffer harm as a result of the Rule. *See Animal Legal Defense Fund, Inc. v. Vilsack,* 111 F.4th 1219, 1227 (D.C. Cir. 2024). Petitioners' members include chemical manufacturers, transporters, and distributors, and scientific organizations that are directly impacted by the regulatory regime under TSCA. *See* ACC Dec. at ¶¶4-5; TCC Dec. at ¶¶4-5; OxyChem Dec. at ¶¶4-6. The Rule governs the evaluation and regulation of chemical substances that are central to Petitioners' members' businesses and operations. Petitioners' members face imminent economic and operational harm in complying with the Rule. *See* ACC Dec. at ¶¶15-19; OxyChem Dec. at ¶¶8-10, 12 (describing impacts and compliance costs); *see also CropLife America v. EPA,* 329 F.3d 876, 883-84 (D.C. Cir. 2003).

Petitioners' member declarations demonstrate a "sufficient likelihood of economic injury to establish standing." *Clinton v. City of N.Y.*, 524 U.S. 417, 432-33 (1998). Additionally, they illustrate why Petitioners' members are injured by having to navigate the flawed and unlawful regulatory processes created by the Rule. *See* ACC Dec. at ¶¶15-19; OxyChem Dec. at ¶¶8-10, 12; *cf. NE Hub Partners v. CNG Transmission Corp.*, 239 F.3d 333, 342 (3d Cir. 2001); *Sayles Hydro Associates v. Maughan*, 985 F.2d 451, 454 (9th Cir. 1993) ("the hardship is the process itself").[5]

These injuries are fairly traceable to the Rule and are redressable by this Court. *See Lujan*, 504 U.S. at 560-61. Petitioners seek to enforce Congressional mandates regarding the scope of the Risk Evaluation Process. A favorable decision by this Court would remove a regulatory burden to the manufacture, development, sale and/or use of their products, which establishes redressability. *See Bennett v. Spear*, 520 U.S. 154, 169 (1997); *see also Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015).

Petitioners also satisfy the second and third *Hunt* factors for associational standing. Seeking the reasonable regulation of chemical substances is germane to

[5] Although these decisions analyzed hardship in the context of a ripeness analysis, the requirement to show hardship from delayed review under the ripeness doctrine "overlaps with the injury in fact facet of standing doctrine." *Navegar, Inc. v. United States*, 103 F.3d 994, 998 (D.C. Cir. 1997).

Petitioners' interests in advocating for and furthering the interests of the chemical industry. *See Am. Trucking Associations, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 247 (D.C. Cir. 2013). Moreover, because Petitioners are not seeking monetary damages, but equitable relief (*i.e.*, vacatur of the Rule), participation of individual members is not required. *See Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 182 (D.C. Cir. 2017).

STANDARD OF REVIEW

The standard set forth in the Administrative Procedure Act ("**APA**") applies to the Court's review of this EPA procedural rule implementing TSCA. 15 U.S.C. § 2618(c)(1). Courts must set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if it:

> . . . has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

Further, the Court must "hold unlawful and set aside" an agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). In determining whether an agency has acted within the

statutory authority Congress granted to it, the Court must utilize "traditional tools of statutory interpretation" and apply the "best" reading of the statute without any deference to the agency's interpretation. *United States Sugar Corp. v. EPA*, 113 F.4th 984, 991-92 (D.C. Cir. 2024) (citing *Loper Bright v. Raimondo*, 144 S.Ct. 2244, 2266 (2024)).

ARGUMENT

I. EPA'S ALL CONDITIONS OF USE APPROACH VIOLATES TSCA AND IS ARBITRARY AND CAPRICIOUS.

In the Rule, EPA adopted a provision stating that it "*will not exclude conditions of use from the scope of the risk evaluation*, but a fit-for-purpose approach may result in varying types and levels of analysis and supporting information for certain conditions of use, consistent with paragraph (b) of this section." 40 C.F.R. § 702.37(a)(4) (emphasis added). This provision formalizes EPA's revised interpretation of TSCA: that Congress *mandated* that it review "all" conditions of use for a chemical substance during the risk evaluation process. However, nowhere in TSCA did Congress mandate this unwieldy review. Rather, TSCA makes clear that Congress intended EPA to review only those conditions of use that pose the greatest potential for risk and regulate only to the extent necessary.

A. The All Conditions of Use Approach is Contrary to the Plain Language of TSCA and Congressional Intent.

i. TSCA's Text Confirms that Congress Did Not Intend for the Agency to Review All Possible Conditions of Use.

EPA states that "the better reading" of TSCA's statutory text is that "EPA lacks authority to exclude conditions of use from the scope of the risk evaluation." 89 Fed. Reg. at 37,031 (further arguing that the agency lacks authority to select among those circumstances for inclusion or exclusion). Contrary to EPA's revisionist interpretation, the plain language of TSCA clearly demonstrates Congress's intent to allow the Administrator to determine which conditions of use pose the greatest potential for risk, and focus its Risk Evaluation Process primarily on those uses. *See U.S. v. Braxtonbrown-Smith*, 278 F.3d 1348, 1352 (D.C. Cir. 2002) (quoting *Estate of Cowart v. Nicklos Drilling Co*., 505 U.S. 469, 474 (1992) ("In construing a statute, the court begins with the plain language of the statute . . . . Where the language is clear, that is the end of judicial inquiry 'in all but the most extraordinary circumstances.'").

At the outset, a critical aspect of construing the plain language of a statute involves "giv[ing] effect, if possible, to every clause or word." *Lui v. SEC*, 591 U.S. 71, 89 (2020); *see also Ctr. for Biological Diversity v. U.S. Int'l Dev. Finance Corp.*, 77 F.4th 679, 688 (D.C. Cir. 2023). Here, giving effect to Congress's inclusion of the term "conditions of use" requires providing boundaries on the scope and extent

of the Risk Evaluations that the agency is required to conduct. *See* 15 U.S.C. § 2605(b)(4)(a). Omitting a term can be as telling of Congressional intent as interpreting the express statutory terms. Had Congress intended for EPA to review "all" conditions of use in every instance, it would have simply included the word "all" to modify "conditions of use" within the many requirements for Risk Evaluations in the statute.

Furthermore, this Court must presume that "Congress says what it means and means what it says." *Simmons v. Himmelreich*, 578 U.S. 621, 627 (2016); *Banks v. Booth*, 3 F.4th 445, 449 (D.C. Cir. 2021). Had Congress intended for EPA to review "all" conditions of use for every chemical substance, it would have said so. Congress could have chosen not to include the "conditions of use" concept altogether and instead instructed EPA to conduct Risk Evaluations for chemical substances, full stop. However, Congress did not do that; instead, it weaved the "conditions of use" concept throughout the relevant provisions with purpose and direction.

The statutory definition of "conditions of use" reinforces that Congress intended EPA to focus on only those uses of a chemical substance that pose the greatest risk. 15 U.S.C. § 2602(4). The term "conditions of use" is defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id*. § 2602(4) (emphasis added).

TSCA directs EPA to examine the hazards and exposures and determine the distinct circumstances under which the chemical can pose risks of injury to health and the environment as opposed to all uses. *See id*. § 2605(b)(2)(F)(i) (requiring that, when conducting risk evaluations, EPA must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance"); *id*. § 2605(b)(2)(F)(iv) (requiring that EPA "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance"). *See also* Section II(A), infra, for a further discussion of EPA's evaluation of risks under individual conditions of use.

The ordinary meaning of the phrase "as determined" provides a clear and unambiguous directive, commanding EPA to determine the uses which should be prioritized and reviewed based on their different potential for exposure and contribution to risk. *See Southwest Airlines Co. v. Saxon*, 596 U.S. 450, 455 (2022) (statutory language must be read according to its "ordinary, contemporary, common meaning"); MERRIAM-WEBSTER DICTIONARY, "Determined" (defined as "to settle or decide by choice of alternatives or possibilities" or "to limit in extent or scope").

Other provisions of TSCA reinforce that Risk Evaluations must be conducted on a reasonable range of individual "conditions of use," rather than on every potential use of a chemical. *See Noble v. Nat'l Ass'n of Letter Carriers, AFL-CIO*, 103 F.4th 45, 50 (D.C. Cir. 2024) ("The [statutory] text must be read in the context

of the entire statute."). EPA's interpretation that it must take the All Conditions of Use Approach improperly renders numerous other provisions superfluous. *See C.F. Commc'n Corp. v. FCC,* 128 F.3d 735, 739 (D.C. Cir. 1997) (citing *Mail Order Ass'n of America v. USPS*, 986 F.2d 509, 515 (D.C. Cir. 1993)) (statutes must be construed "so that no provision is rendered inoperative or superfluous, void or insignificant").

For example, Section 6 of TSCA requires EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. . . ." 15 U.S.C. § 2605(4)(D) (emphasis added). This scoping provision directing EPA to identify the specific "conditions of use" that it will assess during a Risk Evaluation is meaningless if EPA reviews all possible uses of the chemical substance.[6] Through the phrase "expects to consider," Congress clearly contemplated that EPA's discretion would determine which conditions of use are relevant and should be reviewed for a particular chemical substance, rather than suggesting EPA must evaluate all conditions of use. Therefore, EPA's interpretation

[6] Incredibly, in defending the "all uses" approach, EPA "acknowledge[es] that the Agency's expectations at the scoping phase may not always align perfectly with the conditions of use actually considered and assessed in draft and final risk evaluations." 89 Fed. Reg. 37,032.

mandating that "all" conditions of use be reviewed contradicts the plain language of this scoping provision.

The All Conditions of Use Approach is also contrary to the TSCA provision that requires that risk evaluations "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration." *Id.* § 2605(b)(4)(F)(ii). This language highlights the necessity to focus risk evaluations on sentinel exposures or the uses that contribute the highest potential for exposure, resulting in harm to health or the environment. This demonstrates that Congress intended to allow the Administrator to scope the particular uses to be considered, and did not mandate review of all possible conditions of use.

Further, TSCA has a preemption provision that applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D)." *Id.* § 2617(c) (emphasis added). Congress clearly intended that federal preemption would be applied to those specific conditions of use identified by EPA and included in the scope of a risk evaluation. Yet under the Rule, EPA cannot exclude any uses, and risk evaluations must include *all* conditions of use – meaning preemption would apply to all conditions of use *i.e.*, the entire chemical. If Congress intended to universally apply federal preemption to the whole chemical, it would have said so.

See Janko v. Gates, 741 F.3d 136, 140 (D.C. Cir. 2014) ("The preeminent canon of statutory interpretation requires us to presume that the legislature says in a statute what it means and means in a statute what it says there.") (internal citations and quotations omitted).

Finally, EPA's All Conditions of Use Approach is inconsistent with strict statutory timelines under which EPA must commence and complete its review of existing chemicals. *See* 15 U.S.C. § 2605(b)(4)(G) (requiring that risk evaluations be completed "no later than 3 years after the date on which the Administrator initiates the risk evaluation"). It would be infeasible for the agency to thoroughly and effectively review *every possible* scenario or condition of use of a chemical substance within a three-year time frame – indeed EPA previously suggested that it would not be able to meet its statutory deadlines if it evaluated all conditions of use,[7] and, in fact, it has missed many of its statutory deadlines under TSCA since implementing this approach.[8]

Congress included the "conditions of use" and scoping concepts in the statute to focus the extent and scope of the Risk Evaluation Process. EPA's interpretation

[7] *See* 82 Fed. Reg. at 33,728.
[8] *See* U.S. EPA, *Ongoing and Completed Chemical Risk Evaluations under TSCA,* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under (last updated Sept. 23, 2024).

that TSCA mandates a review of "all" conditions of use for every chemical substance cannot be squared with the statutory text.

ii. The Legislative History of TSCA Confirms that Congress Intended for EPA to Consider those "Conditions of Use" with the Greatest Potential to Pose Risk, Not All Conditions of Use.

The legislative history of TSCA reinforces what Congress made clear in the text: that EPA should focus on specific conditions of use, and not "all" conditions of use. *See Eagle Pharmaceuticals, Inc. v. Azar*, 952 F.3d 323, 338 (D.C. Cir. 2020) ("[E]xtrinsic materials, such as legislative history, have a role in statutory interpretation only to the extent they shed a reliable light on the enacting Legislature's understanding of otherwise ambiguous terms.") (internal quotations omitted). As explained below, EPA's approach improperly undermines the Congressional intent of TSCA. *See Braxtonbrown-Smith*, 278 F.3d at 1352 ("The court must avoid an interpretation that undermines congressional purpose considered as a whole when alternative interpretations consistent with the legislative purpose are available").

The history of the 2016 Amendments conveys Congress's intent to provide EPA with the discretion to limit the conditions of use to be evaluated. As stated by one of the bill's lead sponsors, Senator David Vitter (R. La.):

> The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This

> assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult.

162 Cong. Rec. S3511, S3519 (2016) (emphasis added).

This excerpt leaves no doubt that the intent behind Congress's inclusion of the "conditions of use" concept was to allow for the Administrator to act on a chemical-by-chemical basis to select those conditions of use that may pose the greatest risk and to allow EPA to focus its efforts on evaluating the potential risks associated with those uses, while complying with statutory deadlines, and, if necessary, regulating those particular uses accordingly. Although Congress recognized that EPA would begin the review process by considering all uses identified in the scope, it simultaneously clarified that EPA would ultimately focus its Risk Evaluation on only those certain conditions of use that pose the greatest potential for risk.

B. EPA Did Not Adequately Justify Changing its Interpretation to Conclude That TSCA Requires Review of "All" Conditions of Use.

Independently, the Rule should be set aside because EPA did not adequately explain how it reached its conclusion and new interpretations. *See Dickson v. Sec'y of Defense*, 68 F.3d 1396, 1404 (D.C. Cir. 1995) ("The arbitrary and capricious standard of the APA 'mandat[es] that an agency take whatever steps it needs to

provide an explanation that will enable the court to evaluate the agency's rationale at the time of decision.'") (citation omitted); *see also Pub. Citizen v. Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993).

EPA's All Conditions of Use Approach totally departs from its prior interpretations in the 2017 Rule, without adequate justification. In the 2017 Rule, EPA adopted a definition of "conditions of use" identical to the statutory definition and discussed its interpretation of TSCA. *See* 40 C.F.R. § 702.33 (2017). EPA cited both the statute's text and the legislative history of the 2016 Amendments to conclude that it had "discretion to determine the conditions of use that [it] will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk." *See* 82 Fed. Reg. 33,726 (citing 162 Cong. Rec. at S3519-20). EPA further explained that, identifying the "circumstances" that constitute a "condition of use" of each chemical substance will "inevitably involve the exercise of some discretion . . . consistent with the object of conducting a technically sound, manageable evaluation." *Id.*

EPA's Rule reversed its interpretation of the statute, but it failed to provide a reasoned explanation for its diametrically opposed position. *See Dickson*, 68 F.3d at 1404; *Pub. Citizen*, 988 F.2d at 197. EPA now interprets TSCA to mean that the agency lacks discretion to "exclude" or "select among" conditions of use, and may only use discretion when determining whether a "particular circumstance is

intended, known, or reasonably foreseen." 89 Fed. Reg. at 37,032. EPA lists several authorities as justification for the Rule, none of which mandate the All Conditions of Use approach.[9]

Accordingly, because EPA does not adequately justify the reasons for its changed interpretation of "conditions of use" and corresponding sections, the Rule is arbitrary and capricious and must be set aside. *See Dickson*, 68 F.3d at 1405 ("When an agency merely parrots the language of a statute without providing an account of how it reached its results, it has not adequately explained the basis for its decision.").

II. THE WHOLE CHEMICAL APPROACH VIOLATES TSCA AND THE FIFTH AMENDMENT'S DUE PROCESS CLAUSE.

The Rule requires that EPA make a "single" Risk Determination for the entire chemical, previously referred to as the "whole chemical approach." 89 Fed. Reg. at 37,035. Specifically, the Rule states:

> [a]s part of the risk evaluation, EPA will make a *single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment*, without consideration of costs or other non-

[9] EPA cites to the following authorities as support for its changed interpretation in the Rule: (a) the statutory text and structure and Congressional intent; (b) the Ninth Circuit's 2019 decision in *Safer Chemicals, Healthy Families v. EPA*; (c) Executive Order 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis; and (d) "[l]essons learned from the Agency's implementation of the risk evaluation program to date including feedback from the National Academies of Science Engineering and Medicine and scientific peer reviewers."

> risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

40 C.F.R. § 702.39(f)(1) (emphasis added).

The Whole Chemical Approach is contrary to TSCA because it disregards Congress's intent for EPA to review and evaluate chemicals based on how they are used. This approach also violates the due process protections of the regulated community by preventing regulated entities from understanding or having any notice regarding which uses of a chemical actually present an unreasonable risk and will be subject to regulation. Accordingly, the Rule should be set aside.

A. EPA's Whole Chemical Approach is Contrary to the Plain Language of TSCA.

The Whole Chemical Approach will result in EPA issuing one blanket Risk Determination per chemical. Thus, regardless of whether one, some, a substantial number, or all uses of that chemical pose an unreasonable risk, EPA would determine that the chemical as a whole presents an unreasonable risk. 89 Fed. Reg. 37,035 ("Where one or more conditions of use for the chemical present an unreasonable risk, the chemical substance itself necessarily presents an unreasonable risk."). This approach is contrary to TSCA's unambiguous command to determine whether a chemical substance presents unreasonable risk under its "conditions of use." 15 U.S.C. § 2605(b)(4)(A). Nowhere in TSCA's text did Congress mandate review of

the chemical as a whole. In fact, the statute does not even use phrases like "whole chemical," "single risk determination" or "chemical itself."

To interpret a statute, the Court first must look to the plain language of the statute. *See Braxtonbrown-Smith*, 278 F.3d at 1352 (quoting *Estate of Cowart*, 505 U.S. at 474 ("Where the [plain] language [of a statute] is clear, that is the end of judicial inquiry 'in all but the most extraordinary circumstances."). Here, the plain language of TSCA makes clear that Risk Determinations are to be made based on the conditions of use (*i.e.* how a chemical is manufactured, processed, distributed in commerce, used, or disposed of) as decided upon by the Administrator, and not based on the chemical as a whole in every instance without flexibility. Accordingly, for the reasons described below, the Court's inquiry begins and ends with the unambiguous language of TSCA.

TSCA requires EPA to make a Risk Determination of unreasonable risk or no unreasonable risk following completion of the Risk Evaluation. 15 U.S.C. § 2605(b)(4)(A). The statute requires the Administrator to "conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." *Id.* (emphasis added). TSCA does not instruct EPA to evaluate the total risks of a chemical, but each risk, based upon the individual ways the chemical is used.

When read together with other provisions of TSCA emphasizing "conditions of use," namely the scoping and federal preemption provisions, *see infra* Part I.A, it is clear that Congress did not intend to allow EPA to ignore the distinction among such uses by making the risk determination at the whole chemical level. *See e.g., Eagle Pharmaceuticals*, 952 F.3d at 332 (statute must be interpreted "as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into a harmonious whole.") (internal citations omitted). Rather, Congress intended that Risk Evaluations, and their resulting Risk Determinations, be tied to those specific, individual uses of a chemical substance that were determined relevant by the Administrator.

By including the concept of "conditions of use" within TSCA and the statutory provision on Risk Determinations, Congress clearly intended to tie Risk Determinations to the circumstances under which a chemical is likely to be processed or used. The Whole Chemical Approach, however, completely reads out the concept of "conditions of use" from 15 U.S.C. § 2605(b)(4)(A). EPA disregards potential exposures to the substance under specific conditions of use, and therefore EPA cannot differentiate between the uses of the chemical that present the risk, and those that do not. Said another way, a Whole Chemical Approach Risk Evaluation implies a focus on the risk characterization of the substance, and removes evaluation of the potential exposures to the substance (and therefore risks from the substance)

under actual use cases. Such a statutory reading contradicts basic principles of statutory construction and cannot be upheld. *See Natural Resources Defense Council, Inc. v. EPA,* 822 F.2d 104, 113 (D.C. Cir. 1987) ("To read out a statutory provision of a clause setting forth a specific condition or trigger to the provision's applicability is. . . , an entirely unacceptable method of construing statutes").

Similarly, Congress required that, when conducting risk evaluations, EPA must "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance," 15 U.S.C. § 2605(b)(2)(F)(i), and that it "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." *Id.* § 2605(b)(2)(F)(iv). Had Congress instead intended for EPA to determine risk for the chemical as a whole, it would not have included the phrase "the conditions of use of" in either of these provisions.

Finally, the Whole Chemical Approach is contrary to the federal preemption provision of TSCA related to the regulation of chemicals for which EPA makes an "unreasonable" Risk Determination. *See* 15 U.S.C. § 2617(c)(3). Specifically, federal preemption applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 2605(a)." *Id.* (emphasis added). Section 2605(a) in turn requires the Administrator to issue Risk Management rules to regulate chemicals for

which an unreasonable Risk Determination is issued. *Id*. § 2605(a). Read together, federal preemption applies to those particular conditions of uses that are identified in the scope of the Risk Evaluation, not to the whole chemical, *see id*. § 2617(c)(2), because EPA is required to issue Risk Determinations for particular uses, not the whole chemical, and a finding of no unreasonable risk from a condition of use is considered a final agency action.

For these reasons, the Whole Chemical Approach is an unreasonable interpretation of TSCA, and the only harmonious reading requires individual Risk Determinations based on the distinct conditions of use identified in the scope. Nowhere in the statute did Congress intend, direct, or require EPA to make a singular Risk Determination for each existing chemical being evaluated. If this is the process Congress had intended, it would not have included scoping and preemption provisions focusing on the conditions of use.

B. TSCA's Purpose and Legislative History Reinforce What the Text Makes Plain.

The legislative history of TSCA, as originally enacted, and the 2016 Amendments further demonstrate that Congress intended for use-by-use Risk Determinations and not the Whole Chemical Approach. *See Nat'l Treasury Emps. Union v. Fed. Lab. Rels. Auth.*, 691 F.2d 553, 559 (D.C. Cir. 1982) ("In construing ambiguous terms of legislation, the intent of Congress is paramount, and this intent may be appropriately ascertained from relevant legislative history.").

TSCA was not intended to regulate chemical substances for uses that are already regulated under other statutes. *See* 122 Cong. Rec. S16802 (1976); *id*. at S16806 (statement of Sen. Tunney) ("The proposal . . . was viewed largely as an environmental bill designed to plug gaps that existed in the environmental control framework."). EPA's Whole Chemical Approach is directly contrary to this statutory purpose because it reads out sections of TSCA that were intended to focus the scope of EPA's review of existing chemicals.

When Congress enacted TSCA, the drafters recognized that existing federal laws governed certain aspects of chemical regulation, including "air and water laws" and laws governing the "workplace" and "consumer products" but that there were "no existing statutes which authorize the direct control of industrial chemicals themselves for their health or environmental effect . . ." H.R. Rep. No. 114-176, at 166 (2015). The intent of the statute and the policy goals behind it remained "intact" through the 2016 amendments. S. Rep. No. 114-67, at 7 (2015). Specifically, House Report 114-176 states:

> H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals. The Joint Explanatory Statement of the Committee of Conference for the legislation, which is now Title I of TSCA, clearly states that ''[t]he conferees have drawn from both the Senate bill and the House amendment to assure that overlapping or duplicative regulation is avoided.''

Under the flawed Whole Chemical Approach, EPA could regulate any use of the chemical, even if that imposes duplicative regulation of specific uses of the chemical that are regulated under existing federal environmental frameworks, contrary to Congressional intent, and over-regulate uses that pose no unreasonable risk because they are already controlled to an acceptable risk level under other statutes.

For example, even if EPA determines that processing of a certain chemical used in a closed system is already comprehensively regulated under the OSH Act, it could still decide to regulate that use as part of the Whole Chemical Approach (e.g. the use of perchloroethylene as a catalyst regenerator in petroleum refining processes). Conversely, under the best reading of the statute, where Risk Determinations are based on individual conditions of use, EPA would be permitted to make Risk Determinations of unreasonable risk for specific conditions of use of the chemical, and refer any conditions of use that are better or already regulated under existing requirements to the respective agencies/offices with such jurisdiction.

Moreover, under the Whole Chemical Approach, EPA could decide to regulate particular uses of a chemical that do not present an unreasonable risk (simply based on the type of use, not based on other regulations), as a way of addressing the risk of the "whole chemical," even if the basis for the Risk

Determination is an unreasonable risk posed by just one, separate use. Such an illogical possibility was not contemplated in the adoption of TSCA.

C. The Whole Chemical Approach Violates Due Process Protections of the Regulated Community.

EPA's Whole Chemical Approach deprives stakeholders and the regulated community of meaningful notice about what uses will ultimately be subject to regulation through Risk Management. *See Satellite Broad Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987). EPA is failing to make it sufficiently clear, with "ascertainable certainty" its expectations of the regulated community as a result of the Whole Chemical Approach, which violates due process. *Trinity Broad. of Fla., Inc. v. FCC*, 211 F.3d 618, 628 (D.C. Cir. 2000) (citing *General Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995)) (explaining an agency provides proper notice if, "by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with ascertainable certainty, the standards with which the agency expects parties to conform").

The Whole Chemical Argument violates due process protections of the regulated community because it is unclear which conditions of use will ultimately be regulated following a singular Risk Determination. In fact, under this Approach, EPA could decide to regulate conditions of use that would be deemed to pose no unreasonable risk under a Use-by-Use Approach and for which no exposure data or information has been provided to the agency to conclude that the use poses a risk.

As a result, the regulated community is left with more questions than answers and ultimately must "wait and see" how EPA chooses to apply the Whole Chemical Approach in addressing and managing the risks identified in a singular Risk Determination. For example, under the Whole Chemical Approach, a regulated entity that utilizes or sells a certain chemical substance under a condition of use that does not actually pose an unreasonable risk would be left to wonder how strictly it could be regulated and face losses due to market deselection until EPA makes a final regulatory Risk Management decision.

Accordingly, because the regulated community is not left with "ascertainable certainty" as to how its activities may be regulated and the standards with which it may be expected to confirm, the Whole Chemical Approach violates due process protections. *See Trinity Broad. of Fla., Inc.*, 211 F.3d at 628.

III. EPA IGNORED DIRECTIVES UNDER TSCA BY DISREGARDING REQUIRED USE OF PERSONAL PROTECTIVE EQUIPMENT IN CONDUCTING RISK EVALUATIONS.

The Rule added the following new subsection regarding required components of Risk Evaluations:

> In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. *EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination*.

40 C.F.R. § 702.39(f)(2) (emphasis added).

Stated differently, EPA will assume noncompliance with existing OSHA PPE requirements when evaluating worker exposures for manufacturing and industrial uses of chemicals. EPA's No-PPE Assumption ignores TSCA's mandate to consider all "available information on hazards and exposures" and improperly displaces OSHA's authority to regulate workplace conditions.

A. Failure to Consider Existing PPE Requirements for Workers Is Contrary to TSCA.

i. EPA Must Consider All "Available Information" Regarding Exposures, Including Existing Regulatory Requirements.

EPA "shall" assess all "available information on hazards and exposures" as well as "the likely duration [and] intensity . . . of exposures under the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F)(i), (iv). Risk evaluations must also "describe the weight of the scientific evidence for the identified hazard and exposure." *Id*. § (v). EPA "shall take into consideration . . . hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h). "Conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id*. § 2602(4). While TSCA does not define "reasonably available information," EPA promulgated its own definition, which

includes "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations." 40 C.F.R. § 702.33.

Use of PPE by workers to reduce chemical exposure is clearly relevant to the analysis of exposure and its contribution to workplace risk. PPE is often required by OSHA regulations, *see, e.g.*, 29 C.F.R. § 1910.1052 (requiring use of work practice controls, such as PPE, in workplaces with exposures to methylene chloride), and Congress requires every employer to "comply with occupational safety and health standards promulgated under" the Occupational Safety and Health Act ("**OSH Act**"). 29 U.S.C. § 654(a)(2). By turning a blind eye to these existing OSHA regulatory requirements, the Rule will result in Risk Evaluations that fail to comply with TSCA's mandate that EPA "assess available information" because the Rule fails to consider "available information on hazards and exposures," such as existing requirements mandating the use of PPE for certain uses. 15 U.S.C. § 2605(b)(4)(F)(i); *see also Smith v. Spizzirri*, 601 U.S. 472, 472 (2024) (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)) ("The statute's use of the word 'shall' 'creates an obligation impervious to. . . discretion.'"). The Rule's requirement to ignore the use of required PPE also conflicts with Congress's directive to use available information. *See* S. Rep. No. 114-67, at 9 (stating that Congress intended "that EPA systematically search for and identify relevant information that is available").

The Rule's failure to consider the use of PPE, which reduces exposure, conflicts with EPA's duty to evaluate the duration and intensity of exposures. 15 U.S.C. § 2605(b)(4)(F)(iv). The Rule also ignores the statutory definition of "conditions of use," because speculative misuse or non-use of PPE in every case is not "intended, known, or reasonably foreseen" by EPA—indeed, it is *illogical*. *Id*. § 2602(4). Further, the Rule does not comply with EPA's own regulatory definition of "reasonably available information," because the agency clearly can "reasonably generate, obtain, and synthesize" existing regulatory regimes that require the use of PPE in workplaces with chemical exposures. *See* 40 C.F.R. § 702.33.

Ignoring the use of PPE will cause cascading noncompliance with TSCA. Without considering the widespread use of PPE under existing regulatory requirements, Risk Evaluations conducted under the Rule will not comport with the "weight of the scientific evidence" or "best available science" standards because they will overestimate risks by overestimating exposure, leading to inaccurate Risk Management of chemicals not based in science. *See* 15 U.S.C. §§ 2605(b)(4)(F)(v); 2625(h); *see also* ACC, Comment Letter at 7.

EPA also disobeys TSCA's requirement to consult and coordinate with other federal agencies to impose the fewest "burdens of duplicative requirements on those subject" to TSCA. *Id*. § 2608(d). EPA has long described the OSH Act as the "primary statute for protecting the health and safety of workers" that provides "broad

authority" to regulate chemical risks in the workplace. *See* 1,3-Butadiene; Decision To Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 41,393, 41,398 (Oct. 10, 1985). Rather than defer to OSHA's primary authority, the Rule instead uses the overlap between chemical regulation under TSCA and OSHA's authority to regulate workplace safety to overreach into an area that Congress delegated to OSHA for regulation. *See Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990) (quoting *Fed. Mar. Comm'n. v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973)) ("[I]t is fundamental 'that an agency may not bootstrap itself into an area in which it has no jurisdiction.'"). .

ii. Unreasonable Risk Determinations for Every Chemical Are Contrary to TSCA and Congress's Intent.

The consequence of ignoring widespread use of PPE to comply with workplace regulations is that EPA will find an unreasonable risk to workers for nearly every chemical substance EPA evaluates. *See* ACC, Comment Letter at 7. This result is inconsistent with both the plain language of TSCA and Congress's intent, because Risk Evaluations conducted without consideration of the use of PPE will assume a much higher level of exposure to workers than the level that actually exists. *See, e.g.*, Final Revised Unreasonable Risk Determination for 1-Bromopropane at 3 ("EPA has determined that the risk determination [must] not rely on assumptions regarding the use of personal protective equipment (PPE).").

However, TSCA requires EPA to "conduct risk evaluations . . . to determine *whether* a chemical substance presents an unreasonable risk of injury to health or the environment. . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). The statute also states that "a determination by the Administrator . . . that a chemical substance does not present an unreasonable risk of injury to health or the environment" is considered a "final agency action." *Id*. § 2605(i).

The Rule would impermissibly read these provisions out of the statute, because the No-PPE Assumption assumes much higher exposure levels, resulting in arbitrary determinations of unreasonable risk for nearly every chemical for which EPA evaluates risk to workers. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (quoting *United States v. Menasche*, 348 U.S. 528, 538–39 (1955)) (finding that courts should "give effect. . . to every clause and word of a statute"); *see also Young v. UPS, Inc.*, 575 U.S. 206, 226 (2015) (quoting *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001)) (noting that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause is rendered superfluous, void, or insignificant"). This misinterpretation will inevitably lead to arbitrary regulations of workplace exposure to TSCA-regulated chemicals, an absurd result contrary to Congressional intent that fails to give the regulated community certainty regarding which regulations apply between those issued by EPA and OSHA.

Further, Risk Evaluations conducted without consideration of PPE exposure reduction are inconsistent with EPA's own prior policy towards conditions of use. *See* 89 Fed. Reg. at 37,033 (noting that EPA will not review "intentional misuse of a chemical as a condition of use" because intentional misuse scenarios are "unsubstantiated, speculative or otherwise not likely to occur"). Speculative misuse of chemical substances goes beyond the scope of TSCA and is inconsistent with TSCA's legislative history. *See* S. Rep. No. 114-67, at 7 (stating that the term "conditions of use . . . is not intended to include intentional misuse of chemicals"). So too are speculative failures to follow workplace safety requirements.

B. EPA's Authority Under TSCA Does Not Displace OSHA's Authority to Regulate Workplace Exposures.

i. EPA Must Account for OSHA's Existing Regulatory Requirements for Workers.

Unlike EPA, OSHA is the federal agency tasked with regulating the workplace. 29 U.S.C. § 651(b)(3). By statute, OSHA must "by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard." *Id*. § 655(a). Congress required every employer to comply with those standards. *See id.* § 654(a)(2).

OSHA has repeatedly exercised this authority by issuing regulations to protect workers from chemical hazards in the workplace, including by the creation of standards that contain Permissible Exposure Limits ("**PELs**") for certain

chemicals.[10] *See, e.g.*, 29 C.F.R. § 1990.142(a)(2)(i). OSHA requires that employers achieve PELs "primarily through engineering and work practice controls" including "respiratory protection, protective clothing and equipment." *Id*. OSHA has set PELs for approximately 500 chemicals, many of which overlap with chemicals for which EPA has conducted or is conducting Risk Evaluations under TSCA. *See* 29 C.F.R. § 1910.1000; OSHA, *Chemical Hazards and Toxic Substances*, https://www.osha.gov/chemical-hazards (last visited Oct. 10, 2024).

Despite lacking OSHA's expertise in occupational safety, health, and industrial hygiene practices, the Rule disregards existing OSHA regulations that require the use of PPE. *See* 40 C.F.R. § 702.39(f)(2). This is already happening.[11] For example, EPA recently finalized a rule that requires employers to limit inhalation exposures to methylene chloride to 2 ppm[12] based on the No-PPE Assumption[13] and to comply with certain PPE requirements. 40 C.F.R. § 751.109.

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[10] OSHA has acknowledged that many PELs are outdated; however, the proper path forward is for EPA to refer risks that could be mitigated through work practice standards to OSHA, and for OSHA to update PELs accordingly. *See* Permissible Exposure Limits – Annotated Tables, https://www.osha.gov/annotated-pels (last visited 10/10/24); 15 U.S.C. § 2608(a).

[11] *See, e.g.*, EPA, *EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 30, 2021), https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.

[12] Expressed as an eight-hour time-weighted average.

[13] *See* Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254, 39,292 (May 8, 2024) ("[C]ompliance with regulatory controls on workplace exposures to methylene chloride. . . cannot be assumed.").

EPA did so despite an overlapping OSHA regulation that requires employers to limit inhalation exposures to methylene chloride to 25 ppm[14] and take steps to limit exposure risks, including via PPE. 29 C.F.R. § 1910.1052.

The No-PPE Assumption is also currently a critical factor causing EPA to arbitrarily overestimate risks exposure, and therefore risk, at the Risk Evaluation and Risk Determination stages. For instance, the draft Risk Evaluation for formaldehyde includes an "occupational exposure value" of 0.011 ppm[15] (even though naturally occurring indoor air concentrations are much higher, ranging from 0.02 to 4 ppm), when OSHA's preexisting PEL for the same chemical is significantly higher at 0.75 ppm. 29 C.F.R. § 1910.1048. Similarly, the draft Risk Determination for 1,4 dioxane includes an Existing Chemical Exposure Limit of 0.055 ppm,[16] when OSHA's PEL for the same chemical is 100 ppm. 29 C.F.R. § 1910.1000 at Table Z-1. EPA's promulgation of these conservatively low exposure limits without considering OSHA's pre-existing PEL and PPE risk mitigation measures fails to comply with TSCA's mandate to evaluate all "available information on hazards and exposures." 15 U.S.C. § 2605(b)(4)(F)(i). This practice results in EPA arbitrarily overestimating

[14] Expressed as an eight hour time-weighted average.
[15] EPA, *Draft Human Health Risk Assessment for Formaldehyde* (March 2024) https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf.
[16] EPA, *Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1,4-Dioxane* (Aug. 8, 2023), https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0039/content.pdf.

exposures and risks that have already been addressed by the agency tasked with worker protection. *Id*.

ii. TSCA Is Not, and Was Not Intended to Be, a Worker Protection Law.

TSCA mandates that EPA *must* evaluate the risks to "potentially exposed or susceptible subpopulations," which *may* include workers where they are "identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. §§ 2605(b)(4)(A), 2602(12). In other words, if EPA determines that workers are not relevant to the Risk Evaluation under the identified conditions of use, EPA is not required to assess risks to workers. Accounting for the use of PPE and the regulation of workplace exposure by OSHA are obvious reasons that potential workplace exposure does not require EPA to assess risks to workers in every instance. But as a result of the Rule, EPA has focused on workers in all eleven Risk Evaluations it has finalized to date.[17]

Further, TSCA recognizes that regulation by EPA as a result of a faulty Risk Evaluation is not the best approach if regulation by another agency, such as OSHA, is more appropriate. The Rule ignores this option by assuming workers are not following OSHA regulations. Specifically, TSCA contains a mechanism for EPA to refer risks to other agencies where EPA determines that the risk "*may* be prevented

[17] *See Ongoing and Completed Chemical Risk Evaluations Under TSCA, supra.*

or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator." 15 U.S.C. § 2608(a)(1) (emphasis added). Notably, this is a very low bar, as Congress could have required referral when EPA finds that risk "would" or "may likely" be prevented or reduced by another agency, but it did not. Regardless, if the other agency acts upon EPA's referral, TSCA prohibits EPA from further consideration of those risks. *Id*. § 2608(a)(2). If the other agency already regulates the condition of use, or appropriate portion thereof, EPA should consider those regulations in its Risk Evaluation.

Applying this in context, TSCA requires EPA to refer regulation of TSCA chemicals that pose unreasonable risks to workers to OSHA if regulation under the OSH Act *may* prevent or reduce risks of chemical exposure in the workplace. And only if the referral agency fails to act may EPA proceed to regulate those risks to workers. Yet, EPA impermissibly reads this process out of the statute by forbidding consideration of preexisting OSHA regulations, including PELs and work practice controls such as PPE. *See Duncan*, 533 U.S. at 174.

In addition to the express language of TSCA, Congress explicitly stated in a report accompanying the original draft legislation that it did not intend for EPA to evaluate risks to workers in every instance or turn TSCA into a full worker protection law. Specifically, it stated:

> The requirements prescribed by the Administrator under [TSCA] may provide protection for employees in the workplace…[; however,] none

> of the authorities [under TSCA] should be construed as authorizing the Administrator to issue workplace standards directly regulating such matters….Such direct regulation of the workplace falls under the jurisdiction of the Occupational Safety and Health Act of 1970 not under this bill.

H. Rep. NO. 94-1341, at 34 (1976). Congress intended "that any requirement prescribed under [TSCA] be the least burdensome possible for those subject to the requirement and for society while providing an adequate margin of protection against the unreasonable risk." *Id*.

The intent to avoid overburdensome, duplicative regulation continued during the drafting of the 2016 Amendments. There, Congress noted that its goal was to "encourage decisions that avoid confusion, complication, and duplication." H. Rep. No. 114-176, at 28. The Committee on Energy and Commerce instructed EPA to "respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety. Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls." *Id*. at 28–29. The Rule directly contradicts this intent by disregarding OSHA's existing requirements regarding use of PPE in workplaces with certain chemical exposures.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request this Court grant the petitions for review and vacate the Rule as arbitrary, capricious, not in accordance with law, and in excess of EPA's statutory authority.

Respectfully submitted,

/s/ Rafe Petersen
Rafe Petersen
Meaghan Colligan
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

Attorneys for Petitioners Texas Chemistry Council and American Chemistry Council

/s/ David Y. Chung
David Y. Chung
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
Tel.: (202) 624-2567

Attorney for Petitioners American Fuel & Petrochemical Manufacturers and American Petroleum Institute

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I hereby that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and the Court's order dated September 9, 2024 because it contains 10,717 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), according to the count of Microsoft Word.

I further certify that this brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman font.

/s/ Rafe Petersen
Rafe Petersen

/s/ David Y. Chung
David Y. Chung

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of October, 2024, the foregoing Opening Brief of Petitioners has been served on all registered counsel through the Court's electronic filing system.

/s/ Rafe Petersen
Rafe Petersen

/s/ David Y. Chung
David Y. Chung

ORAL ARGUMENT NOT YET SCHEDULED

Docket No. 24-1151
Consolidated with Docket Nos. 24-1185, 24-1182, 24-1202, 24-123

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEXAS CHEMISTRY COUNCIL and
AMERICAN CHEMISTRY COUNCIL, et al.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

OLIN CORPORATION, et al.

Intervenors.

On Petition for Review of Final Action by the
U.S. Environmental Protection Agency

ADDENDUM TO INDUSTRY PETITIONERS' OPENING BRIEF

Rafe Petersen
Meaghan A. Colligan
HOLLAND & KNIGHT LLP
800 17th Street N.W.
Suite 1100
Washington, D.C. 20006
Rafe.Petersen@hklaw.com
Meaghan.Colligan@hklaw.com
Tel.: (202) 419-2481

Attorney for Petitioners, Texas Chemistry Council and American Chemistry Council

David Y. Chung
CROWELL & MORING LLP
1001 Pennsylvania Avenue N.W.
Washington, D.C. 20004
DChung@crowell.com
Tel.: (202) 624-2567

Attorney for Petitioners, American Fuel & Petrochemical Manufacturers and American Petroleum Institute

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Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (5698)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2602

§ 2602. Definitions

Effective: June 22, 2016
Currentness

As used in this chapter:

(1) the [1] term "Administrator" means the Administrator of the Environmental Protection Agency.

(2)(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including--

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

(B) Such term does not include--

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term "commerce" means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(4) The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(5) The terms "distribute in commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(6) The term "environment" includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

(7) The term "guidance" means any significant written guidance of general applicability prepared by the Administrator.

(8) The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.

(9) The term "manufacture" means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture.

(10) The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

(11) The term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title.

(12) The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

(13) The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce--

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

(14) The term "processor" means any person who processes a chemical substance or mixture.

(15) The term "protocols and methodologies for the development of information" means a prescription of--

(A) the--

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which information for a chemical substance or mixture are to be developed and any analysis that is to be performed on such information, and

(B) to the extent necessary to assure that information respecting such effects and characteristics are reliable and adequate--

(i) the manner in which such information are [2] to be developed,

(ii) the specification of any test protocol or methodology to be employed in the development of such information, and

(iii) such other requirements as are necessary to provide such assurance.

(16) The term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(17) The term "United States", when used in the geographic sense, means all of the States.

CREDIT(S)

(Pub.L. 94-469, Title I, § 3, Oct. 11, 1976, 90 Stat. 2004; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 100-418, Title I, § 1214(e)(1), Aug. 23, 1988, 102 Stat. 1156; Pub.L. 114-92, Div. A, Title III, § 315, Nov. 25, 2015, 129 Stat. 791; Pub.L. 114-182, Title I, §§ 3, 19(c), June 22, 2016, 130 Stat. 448, 505.)

Notes of Decisions (5)

Footnotes

1 So in original. Probably should be capitalized.

2 So in original. Probably should be "is".

15 U.S.C.A. § 2602, 15 USCA § 2602
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2605

§ 2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures

Effective: June 22, 2016
Currentness

(a) Scope of regulation

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement--

(A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) Risk evaluations

(1) Prioritization for risk evaluations

(A) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(B) Identification of priorities for risk evaluation

(i) High-priority substances

The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

(ii) Low-priority substances

The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

(C) Information request and review and proposed and final prioritization designation

The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes--

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 2603(a)(2)(B) of this title, subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

(2) Initial risk evaluations and subsequent designations of high- and low-priority substances

(A) Initial risk evaluations

Not later than 180 days after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

(B) Additional risk evaluations

Not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-

priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

(C) Continuing designations and risk evaluations

The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

(D) Preference

In designating high-priority substances, the Administrator shall give preference to--

(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(E) Metals and metal compounds

In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(3) Initiation of risk evaluations; designations

(A) Risk evaluation initiation

Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

(B) Revision

The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

(C) Ongoing designations

The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

(4) Risk evaluation process and deadlines

(A) In general

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

(B) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) Requirement

The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance--

(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

(D) Scope

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

(E) Limitation and criteria

(i) Percentage requirements

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is--

(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

(II) not more than 50 percent.

(ii) Requested risk evaluations

Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 2625(b) of this title, and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

(iii) Preference

In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

(iv) Exceptions

(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 2617(b) of this title.

(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

(F) Requirements

In conducting a risk evaluation under this subsection, the Administrator shall--

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure.

(G) Deadlines

The Administrator--

(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph (C); and

(ii) may extend the deadline for a risk evaluation for not more than 6 months.

(H) Notice and comment

The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

(c) Promulgation of subsection (a) rules

(1) Deadlines

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator--

(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

(C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

(2) Requirements for rule

(A) Statement of effects

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to--

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, including consideration of--

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) Selecting requirements

In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

(C) Consideration of alternatives

Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

(D) Replacement parts

(i) In general

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) Definitions

In this subparagraph--

(I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

(E) Articles

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

(3) Procedures

When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of Title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also--

(A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;

(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

(C) promulgate a final rule based on the matter in the rulemaking record; and

(D) make and publish with the rule the determination described in subsection (a).

(d) Effective date

(1) In general

In any rule under subsection (a), the Administrator shall--

(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

(B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

(E) provide for a reasonable transition period.

(2) Variability

As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3)(A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if--

(i) the Administrator determines that--

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.

(e) Polychlorinated biphenyls

(1) Within six months after January 1, 1977, the Administrator shall promulgate rules to--

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)--

(i) no person may manufacture any polychlorinated biphenyl after two years after January 1, 1977, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that--

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after October 11, 1976.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraph (3) of subsection (c).

(5) This subsection does not limit the authority of the Administrator, under any other provision of this chapter or any other Federal law, to take action respecting any polychlorinated biphenyl.

(f) Mercury

(1) Prohibition on sale, distribution, or transfer of elemental mercury by Federal agencies

Except as provided in paragraph (2), effective beginning on October 14, 2008, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

(2) Exceptions

Paragraph (1) shall not apply to--

(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this chapter; or

(B) a conveyance, sale, distribution, or transfer of coal.

(3) Leases of Federal coal

Nothing in this subsection prohibits the leasing of coal.

(g) Exemptions

(1) Criteria for exemption

The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that--

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

(2) Exemption analysis and statement

In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

(3) Period of exemption

The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

(4) Conditions

As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

(h) Chemicals that are persistent, bioaccumulative, and toxic

(1) Expedited action

Not later than 3 years after June 22, 2016, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments--

(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a

review under section 2604 of this title, or entered into a consent agreement under section 2603 of this title, prior to June 22, 2016; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) No risk evaluation required

The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

(3) Final rule

Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

(4) Selecting restrictions

In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

(5) Relationship to subsection (b)

If, at any time prior to the date that is 90 days after June 22, 2016, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

(i) Final agency action

Under this section and subject to section 2617 of this title--

(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and

(2) a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

(j) Definition

For the purposes of this chapter, the term "requirement" as used in this section shall not displace statutory or common law.

CREDIT(S)

(Pub.L. 94-469, Title I, § 6, Oct. 11, 1976, 90 Stat. 2020; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 109-364, Div. A, Title III, § 317(a), Oct. 17, 2006, 120 Stat. 2142; Pub.L. 110-414, § 3, Oct. 14, 2008, 122 Stat. 4342; Pub.L. 114-182, Title I, § 6, June 22, 2016, 130 Stat. 460.)

Notes of Decisions (46)

15 U.S.C.A. § 2605, 15 USCA § 2605
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2608

§ 2608. Relationship to other Federal laws

Effective: June 22, 2016
Currentness

(a) Laws not administered by the Administrator

(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency--

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either--

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities,

the Administrator may not take any action under section 2605(a) or 2606 of this title with respect to such risk.

(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not--

(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

(B)(i) respond under paragraph (1) within the timeframe specified by the Administrator in the report; and

(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

(4) If an agency to which a report is submitted under paragraph (1) does not take the actions described in subparagraph (A) or (B) of paragraph (3), the Administrator shall--

(A) initiate or complete appropriate action under section 2605(a) of this title; or

(B) take any action authorized or required under section 2606 of this title, as applicable.

(5) This subsection shall not relieve the Administrator of any obligation to take any appropriate action under section 2605(a) or 2606 of this title to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).

(6) If the Administrator has initiated action under section 2605(a) or 2606 of this title with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) Laws administered by the Administrator

(1) The Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions

taken under this chapter. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk.

(c) Occupational safety and health

In exercising any authority under this chapter, the Administrator shall not, for purposes of section 653(b)(1) of Title 29, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) Coordination

In administering this chapter, the Administrator shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other purposes. The Administrator shall, in the report required by section 2629 of this title, report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this chapter with the authority granted under other Acts referred to in subsection (b).

(e) Exposure information

In addition to the requirements of subsection (a), if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.

CREDIT(S)

(Pub.L. 94-469, Title I, § 9, Oct. 11, 1976, 90 Stat. 2030; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, §§ 9, 19(h), June 22, 2016, 130 Stat. 476, 507.)

15 U.S.C.A. § 2608, 15 USCA § 2608
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2617

§ 2617. Preemption

Effective: June 22, 2016
Currentness

(a) In general

(1) Establishment or enforcement

Except as otherwise provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

(A) Development of information

A statute or administrative action to require the development of information about a chemical substance or category of chemical substances that is reasonably likely to produce the same information required under section 2603, 2604, or 2605 of this title in--

(i) a rule promulgated by the Administrator;

(ii) a consent agreement entered into by the Administrator; or

(iii) an order issued by the Administrator.

(B) Chemical substances found not to present an unreasonable risk or restricted

A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance--

(i) for which the determination described in section 2605(i)(1) of this title is made, consistent with the scope of the risk evaluation under section 2605(b)(4)(D) of this title; or

(ii) for which a final rule is promulgated under section 2605(a) of this title, after the effective date of the rule issued under section 2605(a) of this title for the chemical substance, consistent with the scope of the risk evaluation under section 2605(b)(4)(D) of this title.

(C) Significant new use

A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 2604 of this title.

(2) Effective date of preemption

Under this subsection, Federal preemption of statutes and administrative actions applicable to specific chemical substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

(b) New statutes, criminal penalties, or administrative actions creating prohibitions or other restrictions

(1) In general

Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines the scope of a risk evaluation for a chemical substance under section 2605(b)(4)(D) of this title and ending on the date on which the deadline established pursuant to section 2605(b)(4)(G) of this title for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation under section 2605(b)(4)(C) of this title, whichever is earlier, no State or political subdivision of a State may establish a statute, criminal penalty, or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce, or use of such chemical substance that is a high-priority substance designated under section 2605(b)(1)(B)(i) of this title.

(2) Effect of subsection

This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, criminal penalty assessed, or administrative action taken, prior to the date on which the Administrator defines and publishes the scope of a risk evaluation under section 2605(b)(4)(D) of this title.

(c) Scope of preemption

Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only to--

(1) with respect to subsection (a)(1)(A), the chemical substances or category of chemical substances subject to a rule, order, or consent agreement under section 2603, 2604, or 2605 of this title;

(2) with respect to subsection (b), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 2605(b)(4)(D) of this title;

(3) with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 2605(a) or 2605(i)(1) of this title; or

(4) with respect to subsection (a)(1)(C), the uses of such chemical substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 2604 of this title.

(d) Exceptions

(1) No preemption of statutes and administrative actions

(A) In general

Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that--

(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

(ii) implements a reporting, monitoring, or other information obligation for the chemical substance not otherwise required by the Administrator under this chapter or required under any other Federal law;

(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action--

(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the risk evaluation published pursuant to section 2605(b)(4)(D) of this title, but is inconsistent with the action of the Administrator; or

(bb) would cause a violation of the applicable action by the Administrator under section 2604 or 2605 of this title; or

(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

(B) Identical requirements

(i) In general

The penalties and other sanctions applicable under a law of a State or political subdivision of a State in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 2615 of this title.

(ii) Penalties

In the case of an identical requirement--

(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has assessed an adequate penalty under section 2615 of this title; and

(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 2615 of this title.

(2) Applicability to certain rules or orders

(A) Prior rules and orders

Nothing in this section shall be construed as modifying the preemptive effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this chapter prior to that effective date.

(B) Certain chemical substances and mixtures

With respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 2605 of this title prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with respect to manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, nothing in this section shall be construed as modifying the preemptive effect of this section as in effect prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act of any rule or order that is promulgated or issued with respect to such chemical substance or mixture under section 2605 of this title after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under section 2605(b)(1)(B)(i) of this title, the identification of that chemical substance under section 2605(b)(2)(A) of this title, or the selection of that chemical substance for risk evaluation under section 2605(b)(4)(E)(iv)(II) of this title.

(e) Preservation of certain laws

(1) In general

Nothing in this chapter, subject to subsection (g) of this section, shall--

(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken or requirement imposed or requirement enacted relating to a specific chemical substance before April 22, 2016, under the authority of a law of the State or political subdivision of the State that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

(2) Effect of subsection

This subsection does not affect, modify, or alter the relationship between Federal law and laws of a State or political subdivision of a State pursuant to any other Federal law.

(f) Waivers

(1) Discretionary exemptions

Upon application of a State or political subdivision of a State, the Administrator may, by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute, criminal penalty, or administrative action of that State or political subdivision of the State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that--

(A) compelling conditions warrant granting the waiver to protect health or the environment;

(B) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(C) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(D) in the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is designed to address a risk of a chemical substance, under the conditions of use, that was identified--

(i) consistent with the best available science;

(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

(iii) based on the weight of the scientific evidence.

(2) Required exemptions

Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that--

(A)(i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(iii) the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) no later than the date that is 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under the rule promulgated pursuant to section 2605(b)(1)(A) of this title, or the date on which the Administrator publishes the scope of the risk evaluation for a chemical substance under section 2605(b)(4)(D) of this title, whichever is sooner, the State or political subdivision of the State has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance.

(3) Determination of a waiver request

The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised--

(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

(B) not later than 110 days after the date on which an application under paragraph (2) is submitted.

(4) Failure to make a determination

If the Administrator fails to make a determination under paragraph (3)(B) during the 110-day period beginning on the date on which an application under paragraph (2) is submitted, the statute or administrative action of the State or political subdivision of the State that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

(5) Notice and comment

Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of a State under this subsection shall be subject to public notice and comment.

(6) Final agency action

The decision of the Administrator on the application of a State or political subdivision of a State shall be--

(A) considered to be a final agency action; and

(B) subject to judicial review.

(7) Duration of waivers

A waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect until such time as the Administrator publishes the risk evaluation under section 2605(b) of this title.

(8) Judicial review of waivers

Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of a State under paragraph (1) or (2), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

(9) Approval

(A) Automatic approval

If the Administrator fails to meet the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved, effective on the date that is 10 days after the deadline.

(B) Requirements

Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadline under paragraph (3)(B) shall not be considered final agency action or be subject to judicial review or public notice and comment.

(g) Savings

(1) No preemption of common law or statutory causes of action for civil relief or criminal conduct

(A) In general

Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any standard, rule, requirement, standard of performance, risk evaluation, or scientific assessment implemented pursuant

to this chapter, shall be construed to preempt, displace, or supplant any State or Federal common law rights or any State or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

(B) Clarification of no preemption

Notwithstanding any other provision of this chapter, nothing in this chapter, nor any amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

(2) No effect on private remedies

(A) In general

Nothing in this chapter, nor any amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rules, regulations, requirements, risk evaluations, scientific assessments, or orders issued pursuant to this chapter shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

(B) Authority of courts

This chapter does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this chapter or rules, regulations, requirements, standards of performance, risk evaluations, scientific assessments, or orders issued pursuant to this chapter.

CREDIT(S)

(Pub.L. 94-469, Title I, § 18, Oct. 11, 1976, 90 Stat. 2038; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, § 13, June 22, 2016, 130 Stat. 492.)

Notes of Decisions (8)

15 U.S.C.A. § 2617, 15 USCA § 2617
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2618

§ 2618. Judicial review

Effective: June 22, 2016
Currentness

(a) In general

(1)(A) Except as otherwise provided in this subchapter, not later than 60 days after the date on which a rule is promulgated under this subchapter, subchapter II, or subchapter IV, or the date on which an order is issued under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,, [1] any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Except as otherwise provided in this subchapter, courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under this subchapter, other than an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(C)(i) Not later than 60 days after the publication of a designation under section 2605(b)(1)(B)(ii) of this title, any person may commence a civil action to challenge the designation.

(ii) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of Title 28 shall apply to the filing of the record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(b) Additional submissions and presentations; modifications

If in an action under this section to review a rule, or an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.

(c) Standard of review

(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of Title 5, and (ii) except as otherwise provided in subparagraph (B), to review such rule or order in accordance with chapter 7 of Title 5.

(B) Section 706 of Title 5 shall apply to review of a rule or order under this section, except that--

(i) in the case of review of--

(I) a rule under section 2603(a), 2604(b)(4), 2605(a) (including review of the associated determination under section 2605(b)(4)(A)), or 2605(e) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

(II) an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in the record taken as a whole; and

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of Title 5 to be incorporated in the rule or order, except as part of the record, taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of Title 28.

(d) Fees and costs

The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) Other remedies

The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

CREDIT(S)

(Pub.L. 94-469, Title I, § 19, Oct. 11, 1976, 90 Stat. 2039; renumbered Title I and amended Pub.L. 99-519, § 3(b)(2), (c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub.L. 102-550, Title X, § 1021(b)(8), Oct. 28, 1992, 106 Stat. 3923; Pub.L. 114-182, Title I, §§ 14, 19(m), June 22, 2016, 130 Stat. 498, 508.)

Notes of Decisions (17)

Footnotes

1 So in original.

15 U.S.C.A. § 2618, 15 USCA § 2618
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2625

§ 2625. Administration

Effective: December 27, 2022
Currentness

(a) Cooperation of Federal agencies

Upon request by the Administrator, each Federal department and agency is authorized--

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this chapter; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this chapter.

(b) Fees

(1) The Administrator may, by rule, require the payment from any person required to submit information under section 2603 of this title or a notice or other information to be reviewed by the Administrator under section 2604 of this title, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 2605(b) of this title, of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 2603, 2604, and 2605 of this title, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, including contractor costs incurred by the Administrator. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 2603 or 2604 of this title.

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (4).

(3) Fund

(A) Establishment

There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the "Fund"), consisting of such amounts as are deposited in the Fund under this paragraph.

(B) Collection and deposit of fees

Subject to the conditions of subparagraph (C), the Administrator shall collect the fees described in this subsection and deposit those fees in the Fund.

(C) Use of funds by Administrator

Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in paragraph (1).

(D) Accounting and auditing

(i) Accounting

The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of Title 31.

(ii) Auditing

(I) In general

For the purpose of section 3515(c) of Title 31, the Fund shall be considered a component of a covered executive agency.

(II) Components of audit

The annual audit required in accordance with sections 3515 and 3521 of Title 31 of the financial statements of activities carried out using amounts from the Fund shall include an analysis of--

(aa) the fees collected and amounts disbursed under this subsection;

(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this subchapter for which the fees may be used; and

(cc) the number of requests for a risk evaluation made by manufacturers under section 2605(b)(4)(C)(ii) of this title.

(III) Federal responsibility

The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

(4) Amount and adjustment of fees; refunds

In setting fees under this section, the Administrator shall--

(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray--

(i) the lower of--

(I) 25 percent of the costs to the Administrator of carrying out sections 2603, 2604, and 2605 of this title, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, other than the costs to conduct and complete risk evaluations under section 2605(b) of this title; or

(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

(ii) the costs of risk evaluations specified in subparagraph (D);

(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

(D) notwithstanding subparagraph (B)--

(i) except as provided in clause (ii), for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 2605(b)(4)(C)(ii) of this title, establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 2605(b) of this title;

(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 2605(b)(4)(C)(ii) of this title, and which are included in the 2014 update of the TSCA Work Plan for Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the costs to the Administrator of conducting the risk evaluation under section 2605(b) of this title; and

(iii) apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses;

(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under chapter 10 of Title 5 or subchapter II of chapter 5 of Title 5 is applicable with respect to such meetings;

(F) beginning with the fiscal year that is 3 years after June 22, 2016, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray--

(i) approximately but not more than 25 percent of the costs to the Administrator of carrying out sections 2603, 2604, and 2605 of this title, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, other than the costs to conduct and complete risk evaluations requested under section 2605(b)(4)(C)(ii) of this title; and

(ii) the costs of risk evaluations specified in subparagraph (D); and

(G) if a notice submitted under section 2604 of this title is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

(5) Minimum amount of appropriations

Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

(6) Termination

The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after June 22, 2016, unless otherwise reauthorized or modified by Congress.

(c) Action with respect to categories

(1) Any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this chapter with respect to a category of chemical substances or mixtures, any reference in this chapter to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter.

(d) Assistance office

The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this chapter applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) Financial disclosures

(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health and Human Services who--

(A) performs any function or duty under this chapter, and

(B) has any known financial interest (i) in any person subject to this chapter or any rule or order in effect under this chapter, or (ii) in any person who applies for or receives any grant or contract under this chapter,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health and Human Services (hereinafter in this subsection referred to as the "Secretary"), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall--

(A) act within 90 days of January 1, 1977--

(i) to define the term "known financial interests" for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health and Human Services, which are of a nonregulatory or nonpolicymaking nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of Title 18.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

(f) Statement of basis and purpose

Any final order issued under this chapter shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) Assistant Administrator

(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of information, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this chapter, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970.

(h) Scientific standards

In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable--

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of scientific evidence

The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.

(j) Availability of information

Subject to section 2613 of this title, the Administrator shall make available to the public--

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this subchapter;

(2) any information required to be provided to the Administrator under section 2603 of this title;

(3) a nontechnical summary of each risk evaluation conducted under section 2605(b) of this title;

(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies; and

(5) each designation of a chemical substance under section 2605(b) of this title, along with an identification of the information, analysis, and basis used to make the designations.

(k) Reasonably available information

In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

(l) Policies, procedures, and guidance

(1) Development

Not later than 2 years after June 22, 2016, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this chapter made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(2) Review

Not later than 5 years after June 22, 2016, and not less frequently than once every 5 years thereafter, the Administrator shall--

(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this subchapter; and

(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

(3) Testing of chemical substances and mixtures

The policies, procedures, and guidance developed under paragraph (1) applicable to testing chemical substances and mixtures shall--

(A) address how and when the exposure level or exposure potential of a chemical substance or mixture would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and

(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this subchapter, including information relating to potentially exposed or susceptible populations.

(4) Chemical substances with completed risk assessments

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to June 22, 2016, the Administrator may publish proposed and final rules under section 2605(a) of this title that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 2605 of this title.

(5) Guidance

Not later than 1 year after June 22, 2016, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(m) Report to Congress

(1) Initial report

Not later than 6 months after June 22, 2016, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of--

(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 2605(b)(4)(C)(i) of this title, and the resources necessary to conduct the minimum number of risk evaluations required under section 2605(b)(2) of this title;

(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 2605(b)(4)(C)(ii) of this title, the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

(C) the capacity of the Environmental Protection Agency to promulgate rules under section 2605(a) of this title as required based on risk evaluations conducted and published under section 2605(b) of this title; and

(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 2605(b) of this title.

(2) Subsequent reports

The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

(n) Annual plan

(1) In general

The Administrator shall inform the public regarding the schedule and the resources necessary for the completion of each risk evaluation as soon as practicable after initiating the risk evaluation.

(2) Publication of plan

At the beginning of each calendar year, the Administrator shall publish an annual plan that--

(A) identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion;

(B) describes the status of each risk evaluation that has been initiated but not yet completed; and

(C) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

(o) Consultation with Science Advisory Committee on Chemicals

(1) Establishment

Not later than 1 year after June 22, 2016, the Administrator shall establish an advisory committee, to be known as the Science Advisory Committee on Chemicals (referred to in this subsection as the "Committee").

(2) Purpose

The purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter.

(3) Composition

The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.

(4) Schedule

The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

(p) Prior actions

(1) Rules, orders, and exemptions

Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this chapter before June 22, 2016.

(2) Prior-initiated evaluations

Nothing in this chapter prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(3) Actions completed prior to completion of policies, procedures, and guidance

Nothing in this chapter requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this chapter solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

CREDIT(S)

(Pub.L. 94-469, Title I, § 26, Oct. 11, 1976, 90 Stat. 2046; Pub.L. 98-80, § 2(c)(2)(A), Aug. 23, 1983, 97 Stat. 485; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, §§ 17, 19(q), June 22, 2016, 130 Stat. 499, 510; Pub.L. 117-286, § 4(a)(69), Dec. 27, 2022, 136 Stat. 4313.)

Notes of Decisions (1)

15 U.S.C.A. § 2625, 15 USCA § 2625
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 29. Labor
Chapter 15. Occupational Safety and Health (Refs & Annos)

29 U.S.C.A. § 651

§ 651. Congressional statement of findings and declaration of purpose and policy

Currentness

(a) The Congress finds that personal injuries and illnesses arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments.

(b) The Congress declares it to be its purpose and policy, through the exercise of its powers to regulate commerce among the several States and with foreign nations and to provide for the general welfare, to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources--

(1) by encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions;

(2) by providing that employers and employees have separate but dependent responsibilities and rights with respect to achieving safe and healthful working conditions;

(3) by authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under this chapter;

(4) by building upon advances already made through employer and employee initiative for providing safe and healthful working conditions;

(5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems;

(6) by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety;

(7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience;

(8) by providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health;

(9) by providing for the development and promulgation of occupational safety and health standards;

(10) by providing an effective enforcement program which shall include a prohibition against giving advance notice of any inspection and sanctions for any individual violating this prohibition;

(11) by encouraging the States to assume the fullest responsibility for the administration and enforcement of their occupational safety and health laws by providing grants to the States to assist in identifying their needs and responsibilities in the area of occupational safety and health, to develop plans in accordance with the provisions of this chapter, to improve the administration and enforcement of State occupational safety and health laws, and to conduct experimental and demonstration projects in connection therewith;

(12) by providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this chapter and accurately describe the nature of the occupational safety and health problem;

(13) by encouraging joint labor-management efforts to reduce injuries and disease arising out of employment.

CREDIT(S)

(Pub.L. 91-596, § 2, Dec. 29, 1970, 84 Stat. 1590.)

Notes of Decisions (73)

29 U.S.C.A. § 651, 29 USCA § 651
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 29. Labor
Chapter 15. Occupational Safety and Health (Refs & Annos)

29 U.S.C.A. § 654

§ 654. Duties of employers and employees

Currentness

(a) Each employer--

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this chapter which are applicable to his own actions and conduct.

CREDIT(S)

(Pub.L. 91-596, § 5, Dec. 29, 1970, 84 Stat. 1593.)

Notes of Decisions (285)

29 U.S.C.A. § 654, 29 USCA § 654
Current through P.L. 118-106. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter A. General
Part 23. Judicial Review Under EPA—Administered Statutes (Refs & Annos)

40 C.F.R. § 23.5

§ 23.5 Timing of Administrator's action under Toxic Substances Control Act.

Currentness

Unless the Administrator otherwise explicitly provides in promulgating a particular rule or issuing a particular order, the time and date of the Administrator's promulgation or issuance for purposes of section 19(a)(1) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is (a) for a Federal Register document, two weeks after the date when the document is published in the Federal Register, or (b) for any other document, two weeks after it is signed.

SOURCE: 50 FR 7270, Feb. 21, 1985; 53 FR 29322, Aug. 3, 1988; 70 FR 33359, June 8, 2005, unless otherwise noted.

AUTHORITY: Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

40 C.F.R. § 702.33

§ 702.33 Definitions.

Effective: July 2, 2024
Currentness

All definitions in TSCA apply to this subpart. In addition, the following definitions apply:

Act means the Toxic Substances Control Act (TSCA), as amended (15 U.S.C. 2601 et seq.).

Aggregate exposure means the combined exposures from a chemical substance across multiple routes and across multiple pathways.

Conditions of use means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

EPA means the U.S. Environmental Protection Agency.

Pathways means the physical course a chemical substance takes from the source to the organism exposed.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, or overburdened communities.

Reasonably available information means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14.

Routes means the ways a chemical substance enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Sentinel exposure means the exposure from a chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures.

Uncertainty means the imperfect knowledge or lack of precise knowledge of the real world either for specific values of interest or in the description of the system.

Variability means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

40 C.F.R. § 702.35

§ 702.35 Chemical substances subject to risk evaluation.

Effective: July 2, 2024
Currentness

(a) Chemical substances undergoing risk evaluation. A risk evaluation for a chemical substance designated by EPA as a High–Priority Substance pursuant to the prioritization process described in subpart A or initiated at the request of a manufacturer or manufacturers under § 702.45, will be conducted in accordance with this part, subject to § 702.31(c).

(b) Percentage requirements. Pursuant to 15 U.S.C. 2605(b)(4)(E)(i) and in accordance with § 702.45(j)(1), EPA will ensure that the number of chemical substances for which a manufacturer-requested risk evaluation is initiated pursuant to § 702.45(e)(9) is not less than 25%and not more than 50% of the number of chemical substances for which a risk evaluation was initiated upon designation as a High–Priority Substance under subpart A.

(c) Manufacturer-requested risk evaluations for work plan chemical substances. Manufacturer requests for risk evaluations, described in paragraph (a) of this section, for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments will be granted at the discretion of EPA. Such evaluations are not subject to the percentage requirements in paragraph (b) of this section.

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 702. General Practices and Procedures (Refs & Annos)
Subpart B. Procedures for Chemical Substance Risk Evaluations (Refs & Annos)

40 C.F.R. § 702.37

§ 702.37 Evaluation requirements.

Effective: July 2, 2024
Currentness

(a) Considerations.

(1) EPA will use applicable EPA guidance when conducting risk evaluations, as appropriate and where it represents the best available science.

(2) EPA will document that the risk evaluation is consistent with the best available science and based on the weight of the scientific evidence. In determining best available science, EPA shall consider as applicable:

(i) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(ii) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(iii) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(iv) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(v) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

(3) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, based on the weight of the scientific evidence.

(4) EPA will not exclude conditions of use from the scope of the risk evaluation, but a fit-for-purpose approach may result in varying types and levels of analysis and supporting information for certain conditions of use, consistent with paragraph (b) of this section. The extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.

(5) EPA will evaluate chemical substances that are metals or metal compounds in accordance with 15 U.S.C. 2605(b)(2)(E).

(b) Information and information sources.

(1) EPA will base each risk evaluation on reasonably available information.

(2) EPA will apply systematic review methods to assess reasonably available information, as needed to carry out risk evaluations that meet the requirements in TSCA section 26(h) and (i), in a manner that is objective, unbiased, and transparent.

(3) EPA may determine that certain information gaps can be addressed through application of assumptions, uncertainty factors, models, and/or screening to conduct its analysis with respect to the chemical substance, consistent with 15 U.S.C. 2625. The approaches used will be determined by the quality of reasonably available information, the deadlines specified in TSCA section 6(b)(4)(G) for completing the risk evaluation, and the extent to which the information reduces uncertainty.

(4) EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to obtain the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation for such substance. EPA will also use such authorities during the performance of a risk evaluation to obtain information as needed and on a case-by-case basis to ensure that EPA has adequate, reasonably available information to perform the evaluation. Where appropriate, to the extent practicable, and scientifically justified, EPA will require the development of information generated without the use of new testing on vertebrates.

(5) Among other sources of information, EPA will also consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625(o).

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Notes of Decisions (3)

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

40 C.F.R. § 702.39

§ 702.39 Components of risk evaluation.

Effective: July 2, 2024
Currentness

(a) In general. Each risk evaluation will include all of the following components:

(1) A Scope;

(2) A Hazard Assessment;

(3) An Exposure Assessment;

(4) A Risk Characterization; and

(5) A Risk Determination.

(b) Scope of the risk evaluation. The scope of the risk evaluation will include all the following:

(1) The condition(s) of use the EPA expects to consider in the risk evaluation.

(2) The potentially exposed populations, including any potentially exposed or susceptible subpopulations as identified as relevant to the risk evaluation by EPA under the conditions of use that EPA plans to evaluate.

(3) The ecological receptors that EPA plans to evaluate.

(4) The hazards to health and the environment that EPA plans to evaluate.

(5) A description of the reasonably available information and scientific approaches EPA plans to use in the risk evaluation.

(6) A conceptual model that describes the actual or predicted relationships between the chemical substance, its associated conditions of use through predicted exposure scenarios, and the identified human and environmental receptors and human and ecological health hazards.

(7) An analysis plan that includes hypotheses and descriptions about the relationships identified in the conceptual model and the approaches and strategies EPA intends to use to assess exposure and hazard effects, and to characterize risk; and a description, including quality, of the data, information, methods, and models, that EPA intends to use in the analysis and how uncertainty and variability will be characterized.

(8) EPA's plan for peer review consistent with § 702.41.

(c) Hazard assessment.

(1) The hazard assessment process includes the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical substance under the conditions of use.

(2) Hazard information related to potential health and environmental hazards of the chemical substance will be reviewed in a manner consistent with best available science based on the weight of scientific evidence and all assessment methods will be documented.

(3) Consistent with § 702.37(b), information evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, biomonitoring and/or human clinical studies, ecological field data, read across, mechanistic and/or kinetic studies in a variety of test systems. These may include but are not limited to: toxicokinetics and toxicodynamics (e.g., physiological-based pharmacokinetic modeling), and computational toxicology (e.g., high-throughput assays, genomic response assays, data from structure-activity relationships, in silico approaches, and other health effects modeling).

(4) The hazard information relevant to the chemical substance will be evaluated for identified human and environmental receptors, including all identified potentially exposed or susceptible subpopulation(s) determined to be relevant, for the exposure scenarios relating to the conditions of use.

(5) The relationship between the dose of the chemical substance and the occurrence of health and environmental effects or outcomes will be evaluated.

(6) Hazard identification will include an evaluation of the strengths, limitations, and uncertainties associated with the reasonably available information.

(d) Exposure assessment.

(1) Where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) Exposure information related to potential human health or ecological hazards of the chemical substance will be reviewed in a manner consistent with best available science based on the weight of scientific evidence and all assessment methods will be documented.

(3) Consistent with § 702.37(b), information evaluated may include, but would not be limited to: chemical release reports, release or emission scenarios, data and information collected from monitoring or reporting, release estimation approaches and assumptions, biological monitoring data, workplace monitoring data, chemical exposure health data, industry practices with respect to occupational exposure control measures, and exposure modeling.

(4) Chemical-specific factors, including, but not limited to physical-chemical properties and environmental fate and transport parameters, will be examined.

(5) The human health exposure assessment will consider all potentially exposed or susceptible subpopulation(s) determined to be relevant.

(6) Environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological receptors and the exposures considered, including populations and communities, depending on the chemical substance and the ecological characteristic involved.

(7) EPA will describe whether sentinel exposures under the conditions of use were considered and the basis for their consideration.

(8) EPA will consider aggregate exposures to the chemical substance, and, when supported by reasonably available information, consistent with the best available science and based on the weight of scientific evidence, include an aggregate exposure assessment in the risk evaluation, or will otherwise explain in the risk evaluation the basis for not including such an assessment.

(9) EPA will assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other federal statutes.

(e) Risk characterization.

(1) Requirements. To characterize the risks from the chemical substance, EPA will:

(i) Integrate the hazard and exposure assessments into quantitative and/or qualitative estimates relevant to specific risks of injury to health or the environment, including any potentially exposed or susceptible subpopulations identified, under the conditions of use;

(ii) Not consider costs or other non-risk factors; and

(iii) Describe the weight of the scientific evidence for the identified hazards and exposures.

(2) Summary of considerations. EPA will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

(i) Considerations regarding uncertainty and variability. Information about uncertainty and variability in each step of the risk evaluation (e.g., use of default assumptions, scenarios, choice of models, and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks. EPA may describe the uncertainty using a qualitative assessment of the overall strength and limitations of the data and approaches used in the assessment.

(ii) Considerations of data quality. A discussion of data quality (e.g., reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(iii) Considerations of alternative interpretations. If appropriate and relevant, where alternative interpretations are plausible, a discussion of alternative interpretations of the data and analyses will be included.

(iv) Additional considerations for environmental risk. For evaluation of environmental risk, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

(f) Risk determination.

(1) As part of the risk evaluation, EPA will make a single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

(2) In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.

(3) EPA will determine whether a chemical substance does or does not present an unreasonable risk after considering the risks posed under the conditions of use and, where EPA makes a determination of unreasonable risk, EPA will identify the conditions of use that significantly contribute to such determination.

SOURCE: 47 FR 2773, Jan. 19, 1982; 51 FR 6414, Feb. 24, 1986; 82 FR 33747, July 20, 2017; 82 FR 33762, July 20, 2017; 89 FR 37052, May 3, 2024, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605 and 2619.

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

29 C.F.R. § 1990.142

§ 1990.142 Initiation of a rulemaking.

Currentness

Where the Secretary decides to regulate a potential occupational carcinogen, the Secretary shall initiate a rulemaking proceeding in accordance with one of the following procedures, as appropriate.

(a) Notice of proposed rulemakings (section 6(b) of the Act)—

(1) General. The Secretary may issue a notice of proposed rulemaking in the Federal Register, pursuant to section 6(b) of the Act and part 1911 of this chapter. The notice shall provide for no more than a sixty (60) day comment period, and may provide for a hearing, which shall be scheduled for no later than one hundred (100) days after publication of the Notice of Proposed Rulemaking. The commencement of the hearing may be postponed once, for no more than thirty (30) days, for good cause shown.

(2) Provisions of the proposed standard for Category I Potential Carcinogens. Whenever the Secretary issues a notice of proposed rulemaking to regulate a substance as a Category I Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, regulated areas, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, hygiene facilities, medical surveillance, employee information and training, signs and labels, recordkeeping, and employee observation of monitoring as set forth in § 1990.151, unless the Secretary explains why any or all such provisions are not appropriate;

(ii) The model standard set forth in § 1990.151 shall be used as a guideline, and

(iii) The permissible exposure limit shall be achieved primarily through engineering and work practice controls except that if a suitable substitute is available for one or more uses no occupational exposure shall be permitted for those uses.

(3) Provisions of the proposed standard for Category II Potential Carcinogens. Whenever the Secretary issues a Notice of Proposed Rulemaking to regulate a substance as a Category II Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, monitoring, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, recordkeeping and employee observation of monitoring as set forth in § 1990.151, unless the Secretary explains why any or all such provisions are not appropriate; and

(ii) The model standard set forth in § 1990.151 shall be used as a guideline; and

(iii) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the individual rulemaking proceedings. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(b) Emergency temporary standards (section 6(c) of the Act)—

(1) General. The Secretary may issue an Emergency Temporary Standard (ETS) for a Category I Potential Carcinogen in accordance with section 6(c) of the Act.

(2) Provisions of the ETS.

(i) The ETS shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, signs and labels, recordkeeping and employee observation of monitoring, unless the Secretary explains why any or all such provisions are not appropriate.

(ii) The model standard set forth in § 1990.152 shall be used as a guideline.

(iii) The permissible exposure limit shall be achieved through any practicable combination of engineering controls, work practice controls and respiratory protection.

Credits

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

SOURCE: 45 FR 5282, Jan. 22, 1980; 51 FR 24526, 24528, July 7, 1986, unless otherwise noted.

AUTHORITY: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 8–76 (41 FR 25059); 29 CFR Part 1911.

Notes of Decisions (5)

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 29. Labor
Subtitle B. Regulations Relating to Labor
Chapter XVII. Occupational Safety and Health Administration, Department of Labor
Part 1910. Occupational Safety and Health Standards (Refs & Annos)
Subpart Z. Toxic and Hazardous Substances (Refs & Annos)

29 C.F.R. § 1910.1000

§ 1910.1000 Air contaminants.

Effective: May 20, 2017
Currentness

An employee's exposure to any substance listed in Tables Z–1, Z–2, or Z–3 of this section shall be limited in accordance with the requirements of the following paragraphs of this section.

(a) Table Z–1—

(1) Substances with limits preceded by "C"—Ceiling Values. An employee's exposure to any substance in Table Z–1, the exposure limit of which is preceded by a "C", shall at no time exceed the exposure limit given for that substance. If instantaneous monitoring is not feasible, then the ceiling shall be assessed as a 15–minute time weighted average exposure which shall not be exceeded at any time during the working day.

(2) Other substances—8–hour Time Weighted Averages. An employee's exposure to any substance in Table Z–1, the exposure limit of which is not preceded by a "C", shall not exceed the 8–hour Time Weighted Average given for that substance in any 8–hour work shift of a 40–hour work week.

(b) Table Z–2. An employee's exposure to any substance listed in Table Z–2 shall not exceed the exposure limits specified as follows:

(1) 8–hour time weighted averages. An employee's exposure to any substance listed in Table Z–2, in any 8–hour work shift of a 40–hour work week, shall not exceed the 8–hour time weighted average limit given for that substance in Table Z–2.

(2) Acceptable ceiling concentrations. An employee's exposure to a substance listed in Table Z–2 shall not exceed at any time during an 8–hour shift the acceptable ceiling concentration limit given for the substance in the table, except for a time period, and up to a concentration not exceeding the maximum duration and concentration allowed in the column under "acceptable maximum peak above the acceptable ceiling concentration for an 8–hour shift."

(3) Example. During an 8–hour work shift, an employee may be exposed to a concentration of Substance A (with a 10 ppm TWA, 25 ppm ceiling and 50 ppm peak) above 25 ppm (but never above 50 ppm) only for a maximum period of

10 minutes. Such exposure must be compensated by exposures to concentrations less than 10 ppm so that the cumulative exposure for the entire 8–hour work shift does not exceed a weighted average of 10 ppm.

(c) Table Z–3. An employee's exposure to any substance listed in Table Z–3, in any 8–hour work shift of a 40–hour work week, shall not exceed the 8–hour time weighted average limit given for that substance in the table.

(d) Computation formulae. The computation formula which shall apply to employee exposure to more than one substance for which 8–hour time weighted averages are listed in subpart Z of 29 CFR part 1910 in order to determine whether an employee is exposed over the regulatory limit is as follows:

(1)(i) The cumulative exposure for an 8–hour work shift shall be computed as follows:

$E=(C_aT_a+C_bT_b+. . .C_nT_n)\div 8$

Where:

E is the equivalent exposure for the working shift.

C is the concentration during any period of time T where the concentration remains constant.

T is the duration in hours of the exposure at the concentration C.

The value of E shall not exceed the 8–hour time weighted average specified in subpart Z of 29 CFR part 1910 for the substance involved.

(ii) To illustrate the formula prescribed in paragraph (d)(1)(i) of this section, assume that Substance A has an 8–hour time weighted average limit of 100 ppm noted in Table Z–1. Assume that an employee is subject to the following exposure:

Two hours exposure at 150 ppm

Two hours exposure at 75 ppm

Four hours exposure at 50 ppm

Substituting this information in the formula, we have

$(2x150+2x75+4x50)\div 8=81.25$ ppm

Since 81.25 ppm is less than 100 ppm, the 8–hour time weighted average limit, the exposure is acceptable.

(2)(i) In case of a mixture of air contaminants an employer shall compute the equivalent exposure as follows:

$E_m=(C_1\div L_1+C_2\div L_2)+. . .(C_n\div L_n)$

Where:

E_m is the equivalent exposure for the mixture.

C is the concentration of a particular contaminant.

L is the exposure limit for that substance specified in subpart Z of 29 CFR part 1910.

The value of E_m shall not exceed unity (1).

(ii) To illustrate the formula prescribed in paragraph (d)(2)(i) of this section, consider the following exposures:

Substance	Actual concentration of 8-hour exposure (ppm)	8-hour TWA PEL (ppm)
B	500	1,000
C	45	200
D	40	200

Substituting in the formula, we have:

E_m=500÷1,000+45÷200+40÷200

E_m=0.500+0.225+0.200

E_m=0.925

Since E_m is less than unity (1), the exposure combination is within acceptable limits.

(e) To achieve compliance with paragraphs (a) through (d) of this section, administrative or engineering controls must first be determined and implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or any other protective measures shall be used to keep the exposure of employees to air contaminants within the limits prescribed in this section. Any equipment and/or technical measures used for this purpose must be approved for each particular use by a competent industrial hygienist or other technically qualified person. Whenever respirators are used, their use shall comply with 1910.134.

Table Z-1—Limits for Air Contaminants

Substance	CAS No. (c)	ppm (a) [1]	mg/m^3 (b) [1]	Skin designation
Acetaldehyde	75-07-0	200	360	
Acetic acid	64-19-7	10	25	

Acetic anhydride	108-24-7	5	20	
Acetone	67-64-1	1000	2400	
Acetonitrile	75-05-8	40	70	
2-Acetylaminofluorine; see 1910.1014	53-96-3			
Acetylene dichloride; see 1,2-Dichloroethylene.				
Acetylene tetrabromide	79-27-6	1	14	
Acrolein	107-02-8	0.1	0.25	
Acrylamide	79-06-1	.....	0.3	X
Acrylonitrile; see 1910.1045	107-13-1			
Aldrin	309-00-2	.....	0.25	X
Allyl alcohol	107-18-6	2	5	X
Allyl chloride	107-05-1	1	3	
Allyl glycidyl ether (AGE)	106-92-3	(C)10	(C)45	
Allyl propyl disulfide	2179-59-1	2	12	
alpha-Alumina	1344-28-1			
Total dust		.....	15	
Respirable fraction		.....	5	
Aluminum, metal (as Al)	7429-90-5			
Total dust		.....	15	
Respirable fraction		.....	5	
4-Aminodiphenyl; see 1910.1011	92-67-1			
2-Aminoethanol; see Ethanolamine.				
2-Aminopyridine	504-29-0	0.5	2	
Ammonia	7664-41-7	50	35	
Ammonium sulfamate	7773-06-0			
Total dust		.....	15	
Respirable fraction		.....	5	
n-Amyl acetate	628-63-7	100	525	
sec-Amyl acetate	626-38-0	125	650	

Aniline and homologs	62-53-3	5	19	X
Anisidine (o-, p-isomers)	29191-52-4		0.5	X
Antimony and compounds (as Sb)	7440-36-0		0.5	
ANTU (alpha Naphthylthiourea)	86-88-4		0.3	
Arsenic, inorganic compounds (as As); see 1910.1018	7440-38-2			
Arsenic, organic compounds (as As)	7440-38-2		0.5	
Arsine	7784-42-1	0.05	0.2	
Asbestos; see 1910.1001	([4])			
Azinphos-methyl	86-50-0		0.2	X
Barium, soluble compounds (as Ba)	7440-39-3		0.5	
Barium sulfate	7727-43-7			
Total dust			15	
Respirable fraction			5	
Benomyl	17804-35-2			
Total dust			15	
Respirable fraction			5	
Benzene; see 1910.1028	71-43-2			
See Table Z-2 for the limits applicable in the operations or sectors excluded in 1910.1028 [d]				
Benzidine; see 1910.1010	92-87-5			
p-Benzoquinone; see Quinone.				
Benzo(a)pyrene; see Coal tar pitch volatiles.				
Benzoyl peroxide	94-36-0		5	
Benzyl chloride	100-44-7	1	5	
Beryllium and beryllium compounds (as Be); see 1910.1024 [8]	7440-41-7			
Biphenyl; see Diphenyl.				
Bismuth telluride, Undoped	1304-82-1			
Total dust			15	
Respirable fraction			5	

Boron oxide	1303-86-2			
Total dust			15	
Boron trifluoride	7637-07-2	(C)1	(C)3	
Bromine	7726-95-6	0.1	0.7	
Bromoform	75-25-2	0.5	5	X
Butadiene (1,3-Butadiene); See 29 CFR 1910.1051; 29 CFR 1910.19(l)	106-99-0	1 ppm/5 ppm STEL		
Butanethiol; see Butyl mercaptan.				
2-Butanone (Methyl ethyl ketone)	78-93-3	200	590	
2-Butoxyethanol	111-76-2	50	240	X
n-Butyl-acetate	123-86-4	150	710	
sec-Butyl acetate	105-46-4	200	950	
tert-Butyl acetate	540-88-5	200	950	
n-Butyl alcohol	71-36-3	100	300	
sec-Butyl alcohol	78-92-2	150	450	
tert-Butyl alcohol	75-65-0	100	300	
Butylamine	109-73-9	(C)5	(C)15	X
tert-Butyl chromate (as CrO_3); see 1910.1026 [6]	1189-85-1			
n-Butyl glycidyl ether (BGE)	2426-08-6	50	270	
Butyl mercaptan	109-79-5	10	35	
p-tert-Butyltoluene	98-51-1	10	60	
Cadmium (as Cd); see 1910.1027	7440-43-9			
Calcium carbonate	1317-65-3			
Total dust			15	
Respirable fraction			5	
Calcium hydroxide	1305-62-0			
Total dust			15	
Respirable fraction			5	
Calcium oxide	1305-78-8		5	

Calcium silicate	1344-95-2			
Total dust			15	
Respirable fraction			5	
Calcium sulfate	7778-18-9			
Total dust			15	
Respirable fraction			5	
Camphor, synthetic	76-22-2		2	
Carbaryl (Sevin)	63-25-2		5	
Carbon black	1333-86-4		3.5	
Carbon dioxide	124-38-9	5000	9000	
Carbon disulfide	75-15-0		([2])	
Carbon monoxide	630-08-0	50	55	
Carbon tetrachloride	56-23-5		([2])	
Cellulose	9004-34-6			
Total dust			15	
Respirable fraction			5	
Chlordane	57-74-9		0.5	X
Chlorinated camphene	8001-35-2		0.5	X
Chlorinated diphenyl oxide	55720-99-5		0.5	
Chlorine	7782-50-5	(C)1	(C)3	
Chlorine dioxide	10049-04-4	0.1	0.3	
Chlorine trifluoride	7790-91-2	(C)0.1	(C)0.4	
Chloroacetaldehyde	107-20-0	(C)1	(C)3	
a-Chloroacetophenone (Phenacyl chloride)	532-27-4	0.05	0.3	
Chlorobenzene	108-90-7	75	350	
o-Chlorobenzylidene malononitrile	2698-41-1	0.05	0.4	
Chlorobromomethane	74-97-5	200	1050	
2-Chloro-1,3-butadiene; see beta-Chloroprene.				
Chlorodiphenyl (42% Chlorine) (PCB)	53469-21-9		1	X

Chlorodiphenyl (54% Chlorine) (PCB)	11097-69-1		0.5	X
1-Chloro-2,3-epoxypropane; see Epichlorohydrin.				
2-Chloroethanol; see Ethylene chlorohydrin.				
Chloroethylene; see Vinyl chloride.				
Chloroform (Trichloromethane)	67-66-3	(C)50	(C)240	
bis(Chloromethyl) ether; see 1910.1008	542-88-1			
Chloromethyl methyl ether; see 1910.1006	107-30-2			
1-Chloro-1-nitropropane	600-25-9	20	100	
Chloropicrin	76-06-2	0.1	0.7	
beta-Chloroprene	126-99-8	25	90	X
2-Chloro-6-(trichloromethyl) pyridine	1929-82-4			
Total dust			15	
Respirable fraction			5	
Chromium (II) compounds.				
(as Cr)	7440-47-3		0.5	
Chromium (III) compounds.				
(as Cr)	7440-47-3		0.5	
Chromium (VI) compounds; See 1910.1026 [5].				
Chromium metal and insol. salts (as Cr)	7440-47-3		1	
Chrysene; see Coal tar pitch volatiles.				
Clopidol	2971-90-6			
Total dust			15	
Respirable fraction			5	
Coal dust (less than 5% SiO_2), respirable fraction			([3])	
Coal dust (greater than or equal to 5% SiO_2), respirable fraction			([3])	
Coal tar pitch volatiles (benzene soluble fraction), anthracene, BaP, phenanthrene, acridine, chrysene, pyrene	65966-93-2		0.2	
Cobalt metal, dust, and fume (as Co)	7440-48-4		0.1	
Coke oven emissions; see 1910.1029.				

Copper	7440-50-8			
Fume (as Cu)			0.1	
Dusts and mists (as Cu)			1	
Cotton dust [e]; see 1910.1043			1	
Crag herbicide (Sesone)	136-78-7			
Total dust			15	
Respirable fraction			5	
Cresol, all isomers	1319-77-3	5	22	X
Crotonaldehyde	123-73-9; 4170-30-3	2	6	
Cumene	98-82-8	50	245	X
Cyanides (as CN)	([4])		5	X
Cyclohexane	110-82-7	300	1050	
Cyclohexanol	108-93-0	50	200	
Cyclohexanone	108-94-1	50	200	
Cyclohexene	110-83-8	300	1015	
Cyclopentadiene	542-92-7	75	200	
2,4-D (Dichlorophenoxyacetic acid)	94-75-7		10	
Decaborane	17702-41-9	0.05	0.3	X
Demeton (Systox)	8065-48-3		0.1	X
Diacetone alcohol (4-Hydroxy-4-methyl-2-pentanone)	123-42-2	50	240	
1,2-Diaminoethane; see Ethylenediamine.				
Diazomethane	334-88-3	0.2	0.4	
Diborane	19287-45-7	0.1	0.1	
1,2-Dibromo-3-chloropropane (DBCP); see 1910.1044	96-12-8			
1,2-Dibromoethane; see Ethylene dibromide.				
Dibutyl phosphate	107-66-4	1	5	
Dibutyl phthalate	84-74-2		5	

o-Dichlorobenzene	95-50-1	(C)50	(C)300	
p-Dichlorobenzene	106-46-7	75	450	
3,′-Dichlorobenzidine; see 1910.1007	91-94-1			
Dichlorodifluoromethane	75-71-8	1000	4950	
1,3-Dichloro-5,5-dimethyl hydantoin	118-52-5		0.2	
Dichlorodiphenyltrichloroethane (DDT)	50-29-3		1	X
1,1-Dichloroethane	75-34-3	100	400	
1,2-Dichloroethane; see Ethylene dichloride.				
1,2-Dichloroethylene	540-59-0	200	790	
Dichloroethyl ether	111-44-4	(C)15	(C)90	X
Dichloromethane; see Methylene chloride.				
Dichloromonofluoromethane	75-43-4	1000	4200	
1,1-Dichloro-1-nitroethane	594-72-9	(C)10	(C)60	
1,2-Dichloropropane; see Propylene dichloride.				
Dichlorotetrafluoroethane	76-14-2	1000	7000	
Dichlorvos (DDVP)	62-73-7		1	X
Dicyclopentadienyl iron	102-54-5			
Total dust			15	
Respirable fraction			5	
Dieldrin	60-57-1		0.25	X
Diethylamine	109-89-7	25	75	
2-Diethylaminoethanol	100-37-8	10	50	X
Diethyl ether; see Ethyl ether.				
Difluorodibromomethane	75-61-6	100	860	
Diglycidyl ether (DGE)	2238-07-5	(C)0.5	(C)2.8	
Dihydroxybenzene; see Hydroquinone.				
Diisobutyl ketone	108-83-8	50	290	
Diisopropylamine	108-18-9	5	20	X
4-Dimethylaminoazobenzene; see 1910.1015	60-11-7			

Dimethoxymethane; see Methylal.				
Dimethyl acetamide	127-19-5	10	35	X
Dimethylamine	124-40-3	10	18	
Dimethylaminobenzene; see Xylidine				
Dimethylaniline (N,N-Dimethylaniline)	121-69-7	5	25	X
Dimethylbenzene; see Xylene.				
Dimethyl-1,2-dibromo- 2,2-dichloroethyl phosphate	300-76-5		3	
Dimethylformamide	68-12-2	10	30	X
2,6-Dimethyl-4-heptanone; see Diisobutyl ketone.				
1,1-Dimethylhydrazine	57-14-7	0.5	1	X
Dimethylphthalate	131-11-3		5	
Dimethyl sulfate	77-78-1	1	5	X
Dinitrobenzene (all isomers)			1	X
(ortho)	528-29-0			
(meta)	99-65-0			
(para)	100-25-4			
Dinitro-o-cresol	534-52-1		0.2	X
Dinitrotoluene	25321-14-6		1.5	X
Dioxane (Diethylene dioxide)	123-91-1	100	360	X
Diphenyl (Biphenyl)	92-52-4	0.2	1	
Diphenylmethane diisocyanate; see Methylene bisphenyl isocyanate.				
Dipropylene glycol methyl ether	34590-94-8	100	600	X
Di-sec octyl phthalate (Di-(2-ethylhexyl) phthalate)	117-81-7		5	
Emery	12415-34-8			
Total dust			15	
Respirable fraction			5	
Endrin	72-20-8		0.1	X
Epichlorohydrin	106-89-8	5	19	X
EPN	2104-64-5		0.5	X

1,2-Epoxypropane; see Propylene oxide.				
2,3-Epoxy-1-propanol; see Glycidol.				
Ethanethiol; see Ethyl mercaptan.				
Ethanolamine	141-43-5	3	6	
2-Ethoxyethanol (Cellosolve)	110-80-5	200	740	X
2-Ethoxyethyl acetate (Cellosolve acetate)	111-15-9	100	540	X
Ethyl acetate	141-78-6	400	1400	
Ethyl acrylate	140-88-5	25	100	X
Ethyl alcohol (Ethanol)	64-17-5	1000	1900	
Ethylamine	75-04-7	10	18	
Ethyl amyl ketone (5-Methyl-3-heptanone)	541-85-5	25	130	
Ethyl benzene	100-41-4	100	435	
Ethyl bromide	74-96-4	200	890	
Ethyl butyl ketone (3-Heptanone)	106-35-4	50	230	
Ethyl chloride	75-00-3	1000	2600	
Ethyl ether	60-29-7	400	1200	
Ethyl formate	109-94-4	100	300	
Ethyl mercaptan	75-08-1	(C)10	(C)25	
Ethyl silicate	78-10-4	100	850	
Ethylene chlorohydrin	107-07-3	5	16	X
Ethylenediamine	107-15-3	10	25	
Ethylene dibromide	106-93-4	.....	([2])	
Ethylene dichloride (1,2-Dichloroethane)	107-06-2	.....	([2])	
Ethylene glycol dinitrate	628-96-6	(C)0.2	(C)1	X
Ethylene glycol methyl acetate; see Methyl cellosolve acetate.				
Ethyleneimine; see 1910.1012	151-56-4			
Ethylene oxide; see 1910.1047	75-21-8			
Ethylidene chloride; see 1,1-Dichloroethane.				
N-Ethylmorpholine	100-74-3	20	94	X

Ferbam	14484-64-1			
Total dust			15	
Ferrovanadium dust	12604-58-9		1	
Fluorides (as F)	([4])		2.5	
Fluorine	7782-41-4	0.1	0.2	
Fluorotrichloromethane (Trichlorofluoromethane)	75-69-4	1000	5600	
Formaldehyde; see 1910.1048	50-00-0			
Formic acid	64-18-6	5	9	
Furfural	98-01-1	5	20	X
Furfuryl alcohol	98-00-0	50	200	
Grain dust (oat, wheat, barley)			10	
Glycerin (mist)	56-81-5			
Total dust			15	
Respirable fraction			5	
Glycidol	556-52-5	50	150	
Glycol monoethyl ether; see 2-Ethoxyethanol.				
Graphite, natural, respirable dust	7782-42-5		([3])	
Graphite, synthetic				
Total dust			15	
Respirable fraction			5	
Guthion; see Azinphos methyl.				
Gypsum	13397-24-5			
Total dust			15	
Respirable fraction			5	
Hafnium	7440-58-6		0.5	
Heptachlor	76-44-8		0.5	X
Heptane (n-Heptane)	142-82-5	500	2000	
Hexachloroethane	67-72-1	1	10	X

Hexachloronaphthalene	1335-87-1		0.2	X
n-Hexane	110-54-3	500	1800	
2-Hexanone (Methyl n-butyl ketone)	591-78-6	100	410	
Hexone (Methyl isobutyl ketone)	108-10-1	100	410	
sec-Hexyl acetate	108-84-9	50	300	
Hydrazine	302-01-2	1	1.3	X
Hydrogen bromide	10035-10-6	3	10	
Hydrogen chloride	7647-01-0	(C)5	(C)7	
Hydrogen cyanide	74-90-8	10	11	X
Hydrogen fluoride (as F)	7664-39-3		([2])	
Hydrogen peroxide	7722-84-1	1	1.4	
Hydrogen selenide (as Se)	7783-07-5	0.05	0.2	
Hydrogen sulfide	7783-06-4		([2])	
Hydroquinone	123-31-9		2	
Iodine	7553-56-2	(C)0.1	(C)1	
Iron oxide fume	1309-37-1		10	
Isoamyl acetate	123-92-2	100	525	
Isoamyl alcohol (primary and secondary)	123-51-3	100	360	
Isobutyl acetate	110-19-0	150	700	
Isobutyl alcohol	78-83-1	100	300	
Isophorone	78-59-1	25	140	
Isopropyl acetate	108-21-4	250	950	
Isopropyl alcohol	67-63-0	400	980	
Isopropylamine	75-31-0	5	12	
Isopropyl ether	108-20-3	500	2100	
Isopropyl glycidyl ether (IGE)	4016-14-2	50	240	
Kaolin	1332-58-7			
Total dust			15	
Respirable fraction			5	

Ketene	463-51-4	0.5	0.9	
Lead, inorganic (as Pb); see 1910.1025	7439-92-1			
Limestone	1317-65-3			
Total dust			15	
Respirable fraction			5	
Lindane	58-89-9		0.5	X
Lithium hydride	7580-67-8		0.025	
L.P.G. (Liquefied petroleum gas)	68476-85-7	1000	1800	
Magnesite	546-93-0			
Total dust			15	
Respirable fraction			5	
Magnesium oxide fume	1309-48-4			
Total particulate			15	
Malathion	121-75-5			
Total dust			15	X
Maleic anhydride	108-31-6	0.25	1	
Manganese compounds (as Mn)	7439-96-5		(C)5	
Manganese fume (as Mn)	7439-96-5		(C)5	
Marble	1317-65-3			
Total dust			15	
Respirable fraction			5	
Mercury (aryl and inorganic) (as Hg)	7439-97-6		([2])	
Mercury (organo) alkyl compounds (as Hg)	7439-97-6		([2])	
Mercury (vapor) (as Hg)	7439-97-6		([2])	
Mesityl oxide	141-79-7	25	100	
Methanethiol; see Methyl mercaptan.				
Methoxychlor	72-43-5			
Total dust			15	

2-Methoxyethanol (Methyl cellosolve)	109-86-4	25	80	X
2-Methoxyethyl acetate (Methyl cellosolve acetate)	110-49-6	25	120	X
Methyl acetate	79-20-9	200	610	
Methyl acetylene (Propyne)	74-99-7	1000	1650	
Methyl acetylene-propadiene mixture (MAPP)		1000	1800	
Methyl acrylate	96-33-3	10	35	X
Methylal (Dimethoxy-methane)	109-87-5	1000	3100	
Methyl alcohol	67-56-1	200	260	
Methylamine	74-89-5	10	12	
Methyl amyl alcohol; see Methyl isobutyl carbinol.				
Methyl n-amyl ketone	110-43-0	100	465	
Methyl bromide	74-83-9	(C)20	(C)80	X
Methyl butyl ketone; see 2-Hexanone.				
Methyl cellosolve; see 2-Methoxyethanol.				
Methyl cellosolve acetate; see 2-Methoxyethyl acetate.				
Methyl chloride	74-87-3	.....	([2])	
Methyl chloroform (1,1,1-Trichloroethane)	71-55-6	350	1900	
Methylcyclohexane	108-87-2	500	2000	
Methylcyclohexanol	25639-42-3	100	470	
o-Methylcyclohexanone	583-60-8	100	460	X
Methylene chloride	75-09-2	.....	([2])	
Methyl ethyl ketone (MEK); see 2-Butanone.				
Methyl formate	107-31-3	100	250	
Methyl hydrazine (Monomethyl hydrazine)	60-34-4	(C)0.2	(C)0.35	X
Methyl iodide	74-88-4	5	28	X
Methyl isoamyl ketone	110-12-3	100	475	
Methyl isobutyl carbinol	108-11-2	25	100	X
Methyl isobutyl ketone; see Hexone.				
Methyl isocyanate	624-83-9	0.02	0.05	X

Methyl mercaptan	74-93-1	(C)10	(C)20	
Methyl methacrylate	80-62-6	100	410	
Methyl propyl ketone; see 2-Pentanone.				
alpha-Methyl styrene	98-83-9	(C)100	(C)480	
Methylene bisphenyl isocyanate (MDI)	101-68-8	(C)0.02	(C)0.2	
Mica; see Silicates.				
Molybdenum (as Mo)	7439-98-7			
Soluble compounds		.....	5	
Insoluble compounds.				
Total dust		.....	15	
Monomethyl aniline	100-61-8	2	9	X
Monomethyl hydrazine; see Methyl hydrazine.				
Morpholine	110-91-8	20	70	X
Naphtha (Coal tar)	8030-30-6	100	400	
Naphthalene	91-20-3	10	50	
alpha-Naphthylamine; see 1910.1004	134-32-7			
beta-Naphthylamine; see 1910.1009	91-59-8			
Nickel carbonyl (as Ni)	13463-39-3	0.001	0.007	
Nickel, metal and insoluble compounds (as Ni)	7440-02-0	.....	1	
Nickel, soluble compounds (as Ni)	7440-02-0	.....	1	
Nicotine	54-11-5	.....	0.5	X
Nitric acid	7697-37-2	2	5	
Nitric oxide	10102-43-9	25	30	
p-Nitroaniline	100-01-6	1	6	X
Nitrobenzene	98-95-3	1	5	X
p-Nitrochlorobenzene	100-00-5	.....	1	X
4-Nitrodiphenyl; see 1910.1003	92-93-3			
Nitroethane	79-24-3	100	310	
Nitrogen dioxide	10102-44-0	(C)5	(C)9	

Nitrogen trifluoride	7783-54-2	10	29	
Nitroglycerin	55-63-0	(C)0.2	(C)2	X
Nitromethane	75-52-5	100	250	
1-Nitropropane	108-03-2	25	90	
2-Nitropropane	79-46-9	25	90	
N-Nitrosodimethylamine; see 1910.1016.				
Nitrotoluene (all isomers)		5	30	X
o-isomer	88-72-2			
m-isomer	99-08-1			
p-isomer	99-99-0			
Nitrotrichloromethane; see Chloropicrin.				
Octachloronaphthalene	2234-13-1	.....	0.1	X
Octane	111-65-9	500	2350	
Oil mist, mineral	8012-95-1	.....	5	
Osmium tetroxide (as Os)	20816-12-0	.....	0.002	
Oxalic acid	144-62-7	.....	1	
Oxygen difluoride	7783-41-7	0.05	0.1	
Ozone	10028-15-6	0.1	0.2	
Paraquat, respirable dust	4685-14-7; 1910-42-5; 2074-50-2	.....	0.5	X
Parathion	56-38-2	.....	0.1	X
Particulates not otherwise regulated (PNOR) [f].				
Total dust		.....	15	
Respirable fraction		.....	5	
PCB; see Chlorodiphenyl (42% and 54% chlorine).				
Pentaborane	19624-22-7	0.005	0.01	
Pentachloronaphthalene	1321-64-8	.....	0.5	X
Pentachlorophenol	87-86-5	.....	0.5	X

Pentaerythritol	115-77-5			
Total dust			15	
Respirable fraction			5	
Pentane	109-66-0	1000	2950	
2-Pentanone (Methyl propyl ketone)	107-87-9	200	700	
Perchloroethylene (Tetrachloroethylene)	127-18-4		([2])	
Perchloromethyl mercaptan	594-42-3	0.1	0.8	
Perchloryl fluoride	7616-94-6	3	13.5	
Petroleum distillates (Naphtha) (Rubber Solvent)		500	2000	
Phenol	108-95-2	5	19	X
p-Phenylene diamine	106-50-3		0.1	X
Phenyl ether, vapor	101-84-8	1	7	
Phenyl ether-biphenyl mixture, vapor		1	7	
Phenylethylene; see Styrene.				
Phenyl glycidyl ether (PGE)	122-60-1	10	60	
Phenylhydrazine	100-63-0	5	22	X
Phosdrin (Mevinphos)	7786-34-7		0.1	X
Phosgene (Carbonyl chloride)	75-44-5	0.1	0.4	
Phosphine	7803-51-2	0.3	0.4	
Phosphoric acid	7664-38-2		1	
Phosphorus (yellow)	7723-14-0		0.1	
Phosphorus pentachloride	10026-13-8		1	
Phosphorus pentasulfide	1314-80-3		1	
Phosphorus trichloride	7719-12-2	0.5	3	
Phthalic anhydride	85-44-9	2	12	
Picloram	1918-02-1			
Total dust			15	
Respirable fraction			5	
Picric acid	88-89-1		0.1	X

Pindone (2-Pivalyl-1,3-indandione)	83-26-1		0.1	
Plaster of Paris	26499-65-0			
Total dust			15	
Respirable fraction			5	
Platinum (as Pt)	7440-06-4			
Metal				
Soluble salts			0.002	
Portland cement	65997-15-1			
Total dust			15	
Respirable fraction			5	
Propane	74-98-6	1000	1800	
beta-Propriolactone; see 1910.1013	57-57-8			
n-Propyl acetate	109-60-4	200	840	
n-Propyl alcohol	71-23-8	200	500	
n-Propyl nitrate	627-13-4	25	110	
Propylene dichloride	78-87-5	75	350	
Propylene imine	75-55-8	2	5	X
Propylene oxide	75-56-9	100	240	
Propyne; see Methyl acetylene.				
Pyrethrum	8003-34-7		5	
Pyridine	110-86-1	5	15	
Quinone	106-51-4	0.1	0.4	
RDX; see Cyclonite.				
Rhodium (as Rh), metal fume and insoluble compounds	7440-16-6		0.1	
Rhodium (as Rh), soluble compounds	7440-16-6		0.001	
Ronnel	299-84-3		15	
Rotenone	83-79-4		5	
Rouge				
Total dust			15	

Respirable fraction			5	
Selenium compounds (as Se)	7782-49-2		0.2	
Selenium hexafluoride (as Se)	7783-79-1	0.05	0.4	
Silica, amorphous, precipitated and gel	112926-00-8		([3])	
Silica, amorphous, diatomaceous earth, containing less than 1% crystalline silica	61790-53-2		([3])	
Silica, crystalline, respirable dust				
Cristobalite; see 1910.1053 [7]	14464-46-1			
Quartz; see 1910.1053 [7]	14808-60-7			
Tripoli (as quartz); see 1910.1053 [7]	1317-95-9			
Tridymite; see 1910.1053 [7]	15468-32-3			
Silica, fused, respirable dust	60676-86-0		([3])	
Silicates (less than 1% crystalline silica)				
Mica (respirable dust)	12001-26-2		([3])	
Soapstone, total dust			([3])	
Soapstone, respirable dust			([3])	
Talc (containing asbestos); use asbestos limit; see 29 CFR 1910.1001			([3])	
Talc (containing no asbestos), respirable dust	14807-96-6		([3])	
Tremolite, asbestiform; see 1910.1001.				
Silicon	7440-21-3			
Total dust			15	
Respirable fraction			5	
Silicon carbide	409-21-2			
Total dust			15	
Respirable fraction			5	
Silver, metal and soluble compounds (as Ag)	7440-22-4		0.01	
Soapstone; see Silicates.				
Sodium fluoroacetate	62-74-8		0.05	X

Sodium hydroxide	1310-73-2		2	
Starch	9005-25-8			
Total dust			15	
Respirable fraction			5	
Stibine	7803-52-3	0.1	0.5	
Stoddard solvent	8052-41-3	500	2900	
Strychnine	57-24-9		0.15	
Styrene	100-42-5		([2])	
Sucrose	57-50-1			
Total dust			15	
Respirable fraction			5	
Sulfur dioxide	7446-09-5	5	13	
Sulfur hexafluoride	2551-62-4	1000	6000	
Sulfuric acid	7664-93-9		1	
Sulfur monochloride	10025-67-9	1	6	
Sulfur pentafluoride	5714-22-7	0.025	0.25	
Sulfuryl fluoride	2699-79-8	5	20	
Systox; see Demeton.				
2,4,5-T (2,4,5-trichlorophenoxyacetic acid)	93-76-5		10	
Talc; see Silicates.				
Tantalum, metal and oxide dust	7440-25-7		5	
TEDP (Sulfotep)	3689-24-5		0.2	X
Tellurium and compounds (as Te)	13494-80-9		0.1	
Tellurium hexafluoride (as Te)	7783-80-4	0.02	0.2	
Temephos	3383-96-8			
Total dust			15	
Respirable fraction			5	
TEPP (Tetraethyl pyrophosphate)	107-49-3		0.05	X
Terphenyls	26140-60-3	(C)1	(C)9	

1,1,1,2-Tetrachloro- 2,2-difluoroethane	76-11-9	500	4170	
1,1,2,2-Tetrachloro- 1,2-difluoroethane	76-12-0	500	4170	
1,1,2,2-Tetrachloroethane	79-34-5	5	35	X
Tetrachloroethylene; see Perchloroethylene.				
Tetrachloromethane; see Carbon tetrachloride.				
Tetrachloronaphthalene	1335-88-2		2	X
Tetraethyl lead (as Pb)	78-00-2		0.075	X
Tetrahydrofuran	109-99-9	200	590	
Tetramethyl lead (as Pb)	75-74-1		0.075	X
Tetramethyl succinonitrile	3333-52-6	0.5	3	X
Tetranitromethane	509-14-8	1	8	
Tetryl (2,4,6-Trinitrophenylmethylnitramine)	479-45-8		1.5	X
Thallium, soluble compounds (as Tl)	7440-28-0		0.1	X
4,4′-Thiobis (6-tert, Butyl-m-cresol)	96-69-5			
Total dust			15	
Respirable fraction			5	
Thiram	137-26-8		5	
Tin, inorganic compounds (except oxides) (as Sn)	7440-31-5		2	
Tin, organic compounds (as Sn)	7440-31-5		0.1	
Titanium dioxide	13463-67-7			
Total dust			15	
Toluene	108-88-3		([2])	
Toluene-2,4-diisocyanate (TDI)	584-84-9	(C)0.02	(C)0.14	
o-Toluidine	95-53-4	5	22	X
Toxaphene; see Chlorinated camphene.				
Tremolite; see Silicates.				
Tributyl phosphate	126-73-8		5	
1,1,1-Trichloroethane; see Methyl chloroform.				
1,1,2-Trichloroethane	79-00-5	10	45	X

Trichloroethylene	79-01-6		([2])	
Trichloromethane; see Chloroform.				
Trichloronaphthalene	1321-65-9		5	X
1,2,3-Trichloropropane	96-18-4	50	300	
1,1,2-Trichloro-1,2,2- trifluoroethane	76-13-1	1000	7600	
Triethylamine	121-44-8	25	100	
Trifluorobromomethane	75-63-8	1000	6100	
2,4,6-Trinitrophenol; see Picric acid.				
2,4,6-Trinitrophenylmethylnitramine; see Tetryl.				
2,4,6-Trinitrotoluene (TNT)	118-96-7		1.5	X
Triorthocresyl phosphate	78-30-8		0.1	
Triphenyl phosphate	115-86-6		3	
Turpentine	8006-64-2	100	560	
Uranium (as U)	7440-61-1			
Soluble compounds			0.05	
Insoluble compounds			0.25	
Vanadium	1314-62-1			
Respirable dust (as V_2O_5)			(C)0.5	
Fume (as V_2O_5)			(C)0.1	
Vegetable oil mist				
Total dust			15	
Respirable fraction			5	
Vinyl benzene; see Styrene.				
Vinyl chloride; see 1910.1017	75-01-4			
Vinyl cyanide; see Acrylonitrile.				
Vinyl toluene	25013-15-4	100	480	
Warfarin	81-81-2		0.1	
Xylenes (o-, m-, p-isomers)	1330-20-7	100	435	
Xylidine	1300-73-8	5	25	X

Yttrium	7440-65-5		1
Zinc chloride fume	7646-85-7		1
Zinc oxide fume	1314-13-2		5
Zinc oxide	1314-13-2		
Total dust			15
Respirable fraction			5
Zinc stearate	557-05-1		
Total dust			15
Respirable fraction			5
Zirconium compounds (as Zr)	7440-67-7		5

Table Z-2

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift: Concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift: Maximum duration
Benzene[a] (Z37.40-1969)	10 ppm	25 ppm	50 ppm	10 minutes.
Beryllium and beryllium compounds (Z37.29-1970)[d]	2 µg/m^3	5 µg/m^3	25 µg/m^3	30 minutes.
Cadmium fume[b] (Z37.5-1970)	0.1 mg/m^3	0.3 mg/m^3		
Cadmium dust[b] (Z37.5-1970)	0.2 mg/m^3	0.6 mg/m^3		
Carbon disulfide (Z37.3-1968)	20 ppm	30 ppm	100 ppm	30 minutes.
Carbon tetrachloride (Z37.17-1967)	10 ppm	25 ppm	200 ppm	5 min. in any 4 hrs.
Chromic acid and chromates (Z37.7-1971) (as CrO_3)[c]		1 mg/10m^3		
Ethylene dibromide (Z37.31-1970)	20 ppm	30 ppm	50 ppm	5 minutes.

Ethylene dichloride (Z37.21-1969)	50 ppm	100 ppm	200 ppm	5 min. in any 3 hrs.
Fluoride as dust (Z37.28-1969)	2.5 mg/m^3			
Formaldehyde; see 1910.1048				
Hydrogen fluoride (Z37.28-1969)	3 ppm			
Hydrogen sulfide (Z37.2-1966)				10 mins. once, only if no other meas. exp. occurs.
		20 ppm	50 ppm	
Mercury (Z37.8-1971)		1 mg/10m^3		
Methyl chloride (Z37.18-1969)	100 ppm	200 ppm	300 ppm	5 mins. in any 3 hrs.
Methylene Chloride: See § 1910.1052				
Organo (alkyl) mercury (Z37.30-1969)	0.01 mg/m^3	0.04 mg/m^3		
Styrene (Z37.15-1969)	100 ppm	200 ppm	600 ppm	5 mins. in any 3 hrs.
Tetrachloroethylene (Z37.22-1967)	100 ppm	200 ppm	300 ppm	5 mins. in any 3 hrs.
Toluene (Z37.12-1967)	200 ppm	300 ppm	500 ppm	10 minutes.
Trichloroethylene (Z37.19-1967)	100 ppm	200 ppm	300 ppm	5 mins. in any 2 hrs.

TABLE Z-3 Mineral Dusts

Substance	mppcf [a]	mg/m^3
Silica:		
Crystalline		
Quartz (Respirable) [f]	250 [b]	10 mg/m^3 [e]
	IO_2+5	% SIO_2+2

Cristobalite: Use ½ the value calculated from the count or mass formulae for quartz. [f]		
Tridymite: Use ½ the value calculated from the formulae for quartz. [f]		
Amorphous, including natural diatomaceous earth	20	80 mg/m^3
		% SiO_2
Silicates (less than 1% crystalline silica):		
Mica	20	
Soapstone	20	
Talc (not containing asbestos)	20 [c]	
Talc (containing asbestos) Use asbestos limit		
Tremolite, asbestiform (see 29 CFR 1910.1001)		
Portland cement	50	
Graphite (Natural)	15	
Coal Dust:		
Respirable fraction less than 5% SiO_2		2.4 mg/m^3 [e]
		SiO_2+2
Respirable fraction greater than 5% SiO_2		[e] 10 mg/m^3
		% SiO_2+2
Inert or Nuisance Dust: [d]		
Respirable fraction	15	5 mg/m^3
Total dust	50	15 mg/m^3

Note—Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per c.c.

Aerodynamic diameter (unit density sphere)	Percent passing selector
2	90
2.5	75
3.5	50
5.0	25
10	0

The measurements under this note refer to the use of an AEC (now NRC) instrument. The respirable fraction of coal dust is determined with an MRE; the figure corresponding to that of 2.4 mg/m^3 in the table for coal dust is 4.5 mg/m^3.

(f) [Reserved by 71 FR 16673]

Credits

[39 FR 23502, June 27, 1974. Redesignated and amended at 40 FR 23073, May 28, 1975; 42 FR 22525, May 3, 1977; 43 FR 2600, Jan. 17, 1978; 43 FR 5963, Feb. 10, 1978; 43 FR 13563, March 31, 1978; 43 FR 19624, May 5, 1978; 43 FR 27394, June 23, 1978; 43 FR 45809, Oct. 3, 1978; 43 FR 53007, Nov. 14, 1978; 43 FR 57602, Dec. 8, 1978; 46 FR 32022, June 19, 1981; 49 FR 25796, June 22, 1984; 50 FR 51173, Dec. 13, 1985; 51 FR 41477, Nov. 17, 1986; 52 FR 34562, Sept. 11, 1987; 52 FR 46291, Dec. 4, 1987; 54 FR 2920, Jan. 19, 1989; 54 FR 28059, 28061, July 5, 1989; 54 FR 36767, Sept. 5, 1989; 54 FR 41244, Oct. 6, 1989; 54 FR 47513, Nov. 15, 1989; 54 FR 50372, Dec. 6, 1989; 55 FR 3724, Feb. 5, 1990; 55 FR 12819, April 6, 1990; 55 FR 19259, May 9, 1990; 55 FR 46950, Nov. 8, 1990; 57 FR 29205, 29206, July 1, 1992; 57 FR 42388, Sept. 14, 1992; 58 FR 21781, April 23, 1993; 58 FR 35340, June 30, 1993; 58 FR 40191, July 27, 1993; 61 FR 56831, Nov. 4, 1996; 62 FR 1600, Jan. 10, 1997; 62 FR 42018, Aug. 4, 1997; 71 FR 10373, Feb. 28, 2006; 71 FR 16673, April 3, 2006; 71 FR 36008, June 23, 2006; 81 FR 16861, March 25, 2016; 81 FR 31167, May 18, 2016; 81 FR 60272, Sept. 1, 2016; 82 FR 2735, Jan. 9, 2017; 82 FR 8901, Feb. 1, 2017; 82 FR 14439, March 21, 2017]

SOURCE: 39 FR 23502, June 27, 1974; 40 FR 23073, May 28, 1975; 50 FR 37353, Sept. 13, 1985; 50 FR 48758, Nov. 27, 1985; 51 FR 22733, June 20, 1986; 51 FR 24527, July 7, 1986; 51 FR 34597, Sept. 30, 1986; 52 FR 34562, Sept. 11, 1987; 52 FR 46291, Dec. 4, 1987; 54 FR 2920, Jan. 19, 1989; 54 FR 28059, July 5, 1989; 55 FR 3166, Jan. 30, 1990; 55 FR 3327, Jan. 31, 1990; 55 FR 5118, Feb. 13, 1990; 55 FR 12819, April 6, 1990; 56 FR 64175, Dec. 6, 1991; 58 FR 21780, April 23, 1993; 58 FR 35340, June 30, 1993; 59 FR 36699, July 19, 1994; 60 FR 9624, Feb. 21, 1995; 60 FR 33344, June 28, 1995; 61 FR 9242, March 7, 1996; 61 FR 31430, June 20, 1996; 62 FR 42666, Aug. 8, 1997; 63 FR 1285, Jan. 8, 1998; 63 FR 33467, June 18, 1998; 65 FR 76567, Dec. 7, 2000; 66 FR 5324, Jan. 18, 2001; 66 FR 18191, April 6, 2001; 67 FR 67965, Nov. 7, 2002; 70 FR 1141, Jan. 5, 2005; 71 FR 10373, Feb. 28, 2006; 71 FR 16673, April 3, 2006; 71 FR 50188, Aug. 24, 2006; 73 FR 75584, Dec. 12, 2008; 75 FR 12685, March 17, 2010; 76 FR 33607, June 8, 2011; 77 FR 17778, March 26, 2012; 77 FR 19934, April 3, 2012; 79 FR 21848, April 18, 2014; 81 FR 16861, March 25, 2016; 82 FR 2735, Jan. 9, 2017; 83 FR 39360, Aug. 9, 2018; 84 FR 21458, May 14, 2019; 89 FR 81830, Oct. 9, 2024, unless otherwise noted.

AUTHORITY: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 08–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48

FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2007 (72 FR 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.; All of subpart Z issued under 29 U.S.C. 655(b), except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of § 1910.1000. The latter were issued under 29 U.S.C. 655(a).; Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.; Section 1910.1001 also issued under 40 U.S.C. 3704 and 5 U.S.C. 553.; Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.; Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.; Section 1910.1030 also issued under Public Law 106–430, 114 Stat. 1901.; Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Notes of Decisions (180)

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

Footnotes

1 The PELs are 8-hour TWAs unless otherwise noted; a (C) designation denotes a ceiling limit. They are to be determined from breathing-zone air samples.

a Parts of vapor or gas per million parts of contaminated air by volume at 25 °C and 760 torr.

b Milligrams of substance per cubic meter of air. When entry is in this column only, the value is exact; when listed with a ppm entry, it is approximate.

c The CAS number is for information only. Enforcement is based on the substance name. For an entry covering more than one metal compound, measured as the metal, the CAS number for the metal is given—not CAS numbers for the individual compounds.

d The final benzene standard in 1910.1028 applies to all occupational exposures to benzene except in some circumstances the distribution and sale of fuels, sealed containers and pipelines, coke production, oil and gas drilling and production, natural gas processing, and the percentage exclusion for liquid mixtures; for the excepted subsegments, the benzene limits in Table Z-2 apply. See 1910.1028 for specific circumstances.

e This 8-hour TWA applies to respirable dust as measured by a vertical elutriator cotton dust sampler or equivalent instrument. The time-weighted average applies to the cottom waste processing operations of waste recycling (sorting, blending, cleaning and willowing) and garnetting. See also 1910.1043 for cotton dust limits applicable to other sectors.

f All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by the Particulates Not Otherwise Regulated (PNOR) limit which is the same as the inert or nuisance dust limit of Table Z-3.

2 See Table Z-2.

3 See Table Z-3.

4 Varies with compound.

5 See Table Z-2 for the exposure limit for any operations or sectors where the exposure limit in § 1910.1026 is stayed or is otherwise not in effect.

6 If the exposure limit in § 1910.1026 is stayed or is otherwise not in effect, the exposure limit is a ceiling of 0.1 mg/m^3.

7 See Table Z-3 for the exposure limit for any operations or sectors where the exposure limit in § 1910.1053 is stayed or is otherwise not in effect.

8 See Table Z-2 for the exposure limits for any operations or sectors where the exposure limits in § 1910.1024 are stayed or otherwise not in effect.

a This standard applies to the industry segments exempt from the 1 ppm 8–hour TWA and 5 ppm STEL of the benzene standard at 1910.1028.

b This standard applies to any operations or sectors for which the Cadmium standard, 1910.1027, is stayed or otherwise not in effect.

c This standard applies to any operations or sectors for which the exposure limit in the Chromium (VI) standard, § 1910.1026, is stayed or is otherwise not in effect.

d This standard applies to any operations or sectors for which the exposure limits in the beryllium standard, § 1910.1024, are stayed or is otherwise not in effect.

a Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.

b The percentage of crystalline silica in the formula is the amount determined from airborne samples, except in those instances in which other methods have been shown to be applicable.

c Containing less than 1% quartz; if 1% quartz or more, use quartz limit.

d All inert or nuisance dusts, whether mineral, inorganic, or organic, not listed specifically by substance name are covered by this limit, which is the same as the Particulates Not Otherwise Regulated (PNOR) limit in Table Z-1.

e Both concentration and percent quartz for the application of this limit are to be determined from the fraction passing a size-selector with the following characteristics:

f This standard applies to any operations or sectors for which the respirable crystalline silica standard, 1910.1053, is stayed or is otherwise not in effect.

End of Document

Code of Federal Regulations
Title 29. Labor
Subtitle B. Regulations Relating to Labor
Chapter XVII. Occupational Safety and Health Administration, Department of Labor
Part 1910. Occupational Safety and Health Standards (Refs & Annos)
Subpart Z. Toxic and Hazardous Substances (Refs & Annos)

29 C.F.R. § 1910.1048

§ 1910.1048 Formaldehyde.

Effective: July 15, 2019
Currentness

(a) Scope and application. This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde.

(b) Definitions. For purposes of this standard, the following definitions shall apply:

Action level means a concentration of 0.5 part formaldehyde per million parts of air (0.5 ppm) calculated as an eight (8)-hour time-weighted average (TWA) concentration.

Assistant Secretary means the Assistant Secretary of Labor for the Occupational Safety and Health Administration, U.S. Department of Labor, or designee.

Authorized person means any person required by work duties to be present in regulated areas, or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency is any occurrence, such as but not limited to equipment failure, rupture of containers, or failure of control equipment that results in an uncontrolled release of a significant amount of formaldehyde.

Employee exposure means the exposure to airborne formaldehyde which would occur without corrections for protection provided by any respirator that is in use.

Formaldehyde means the chemical substance, HCHO, Chemical Abstracts Service Registry No. 50–00–0.

(c) Permissible Exposure Limit (PEL)—

(1) TWA: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 parts formaldehyde per million parts of air (0.75 ppm) as an 8–hour TWA.

(2) Short Term Exposure Limit (STEL): The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds two parts formaldehyde per million parts of air (2 ppm) as a 15–minute STEL.

(d) Exposure monitoring—

(1) General.

(i) Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to formaldehyde.

(ii) Exception. Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

(iii) When an employee's exposure is determined from representative sampling, the measurements used shall be representative of the employee's full shift or short-term exposure to formaldehyde, as appropriate.

(iv) Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.

(2) Initial monitoring. The employer shall identify all employees who may be exposed at or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.

(i) Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

(ii) The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

(iii) If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer shall promptly monitor the affected employee's exposure.

(3) Periodic monitoring.

(i) The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.

(ii) If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

(iii) If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

(4) Termination of monitoring. The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

(5) Accuracy of monitoring. Monitoring shall be accurate, at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

(6) Employee notification of monitoring results. The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees. If employee exposure is above the PEL, affected employees shall be provided with a description of the corrective actions being taken by the employer to decrease exposure.

(7) Observation of monitoring.

(i) The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde required by this standard.

(ii) When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the clothing and equipment to the observer, require the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

(e) Regulated areas.

(1) Signs.

(i) The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and access ways with signs bearing the following legend:

DANGER

FORMALDEHYDE

MAY CAUSE CANCER

CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION

AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(1)(i) of this section:

DANGER

FORMALDEHYDE

IRRITANT AND POTENTIAL CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(2) The employer shall limit access to regulated areas to authorized persons who have been trained to recognize the hazards of formaldehyde.

(3) An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

(f) Methods of compliance—

(1) Engineering controls and work practices. The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to formaldehyde at or below the TWA and the STEL.

(2) Exception. Whenever the employer has established that feasible engineering and work practice controls cannot reduce employee exposure to or below either of the PELs, the employer shall apply these controls to reduce employee exposures to the extent feasible and shall supplement them with respirators which satisfy this standard.

(g) Respiratory protection—

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls.

(ii) Work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the PELs.

(iv) Emergencies.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with § 1910.134(b) through (d) (except (d)(1)(iii), (d)(3)(iii)(b)(1), and (2)), and (f) through (m), which covers each employee required by this section to use a respirator.

(ii) When employees use air-purifying respirators with chemical cartridges or canisters that do not contain end-of-service-life indicators approved by the National Institute for Occupational Safety and Health, employers must replace these cartridges or canisters as specified by paragraphs (d)(3)(iii)(B)(1) and (B)(2) of 29 CFR 1910.134, or at the end of the workshift, whichever condition occurs first.

(3) Respirator selection.

(i) Employers must:

(A) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

(B) Equip each air-purifying, full facepiece respirator with a canister or cartridge approved for protection against formaldehyde.

(C) For escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the demand or pressure-demand mode; or a full facepiece respirator having a chin-style, or a front-or back-mounted industrial-size, canister or cartridge approved for protection against formaldehyde.

(ii) Employers may substitute an air-purifying, half mask respirator for an air-purifying, full facepiece respirator when they equip the half mask respirator with a cartridge approved for protection against formaldehyde and provide the affected employee with effective gas-proof goggles.

(iii) Employers must provide employees who have difficulty using negative pressure respirators with powered air-purifying respirators permitted for use under paragraph (g)(3)(i)(A) of this standard and that affords adequate protection against formaldehyde exposures.

(h) Protective equipment and clothing. Employers shall comply with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133. When protective equipment or clothing is provided under these provisions, the employer shall provide these protective devices at no cost to the employee and assure that the employee wears them.

(1) Selection. The employer shall select protective clothing and equipment based upon the form of formaldehyde to be encountered, the conditions of use, and the hazard to be prevented.

(i) All contact of the eyes and skin with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of material impervious to formaldehyde and the use of other personal protective equipment, such as goggles and face shields, as appropriate to the operation.

(ii) Contact with irritating or sensitizing materials shall be prevented to the extent necessary to eliminate the hazard.

(iii) Where a face shield is worn, chemical safety goggles are also required if there is a danger of formaldehyde reaching the area of the eye.

(iv) Full body protection shall be worn for entry into areas where concentrations exceed 100 ppm and for emergency reentry into areas of unknown concentration.

(2) Maintenance of protective equipment and clothing.

(i) The employer shall assure that protective equipment and clothing that has become contaminated with formaldehyde is cleaned or laundered before its reuse.

(ii) When formaldehyde-contaminated clothing and equipment is ventilated, the employer shall establish storage areas so that employee exposure is minimized.

(A) Signs. Storage areas for contaminated clothing and equipment shall have signs bearing the following legend:

DANGER

FORMALDEHYDE–CONTAMINATED [CLOTHING] EQUIPMENT

MAY CAUSE CANCER

CAUSES SKIN, EYE AND RESPIRATORY IRRITATION

DO NOT BREATHE VAPOR

DO NOT GET ON SKIN

(B) Labels. The employer shall ensure containers for contaminated clothing and equipment are labeled consistent with the Hazard Communication Standard, § 1910.1200, and shall, as a minimum, include the following:

DANGER

FORMALDEHYDE–CONTAMINATED [CLOTHING] EQUIPMENT

MAY CAUSE CANCER

CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION

DO NOT BREATHE VAPOR

DO NOT GET ON SKIN

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (h)(2)(ii)(A) of this section:

DANGER

FORMALDEHYDE–CONTAMINATED [CLOTHING] EQUIPMENT

AVOID INHALATION AND SKIN CONTACT

(D) Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (h)(2)(ii)(B) of this section:

DANGER

FORMALDEHYDE–CONTAMINATED [CLOTHING] EQUIPMENT

AVOID INHALATION AND SKIN CONTACT

(iii) The employer shall assure that only persons trained to recognize the hazards of formaldehyde remove the contaminated material from the storage area for purposes of cleaning, laundering, or disposal.

(iv) The employer shall assure that no employee takes home equipment or clothing that is contaminated with formaldehyde.

(v) The employer shall repair or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

(vi) The employer shall inform any person who launders, cleans, or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

(i) Hygiene protection.

(1) The employer shall provide change rooms, as described in 29 CFR 1910.141 for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde.

(2) If employees' skin may become splashed with solutions containing 1 percent or greater formaldehyde, for example, because of equipment failure or improper work practices, the employer shall provide conveniently located quick drench showers and assure that affected employees use these facilities immediately.

(3) If there is any possibility that an employee's eyes may be splashed with solutions containing 0.1 percent or greater formaldehyde, the employer shall provide acceptable eyewash facilities within the immediate work area for emergency use.

(j) Housekeeping. For operations involving formaldehyde liquids or gas, the employer shall conduct a program to detect leaks and spills, including regular visual inspections.

(1) Preventative maintenance of equipment, including surveys for leaks, shall be undertaken at regular intervals.

(2) In work areas where spillage may occur, the employer shall make provisions to contain the spill, to decontaminate the work area, and to dispose of the waste.

(3) The employer shall assure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment and trained in proper methods for cleanup and decontamination.

(4) Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde. The employer shall ensure that the labels are in accordance with paragraph (m) of this section.

(k) Emergencies. For each workplace where there is the possibility of an emergency involving formaldehyde, the employer shall assure appropriate procedures are adopted to minimize injury and loss of life. Appropriate procedures shall be implemented in the event of an emergency.

(l) Medical surveillance—

(1) Employees covered.

(i) The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or exceeding the STEL.

(ii) The employer shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, the employer may rely on the evidence that signs and symptoms associated with formaldehyde exposure will occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in material in concentrations less than 0.1 percent.

(2) Examination by a physician. All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(3) Medical disease questionnaire. The employer shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter. The employer shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms indicative of possible overexposure to formaldehyde.

(i) Administration of a medical disease questionnaire, such as in appendix D, which is designed to elicit information on work history, smoking history, any evidence of eye, nose, or throat irritation; chronic airway problems or hyperreactive airway disease: allergic skin conditions or dermatitis; and upper or lower respiratory problems.

(ii) A determination by the physician, based on evaluation of the medical disease questionnaire, of whether a medical examination is necessary for employees not required to wear respirators to reduce exposure to formaldehyde.

(4) Medical examinations. Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde and at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

(i) A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath, or irritation of the eyes.

(ii) Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), and forced expiratory flow (FEF).

(iii) Any other test which the examining physician deems necessary to complete the written opinion.

(iv) Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the increased risk of impairment of their health.

(5) Examinations for employees exposed in an emergency. The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

(i) The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity, and any evidence of eye, nose, or throat irritation.

(ii) Other examinations shall consist of those elements considered appropriate by the examining physician.

(6) Information provided to the physician. The employer shall provide the following information to the examining physician:

(i) A copy of this standard and appendix A, C, D, and E;

(ii) A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde;

(iii) The representative exposure level for the employee's job assignment;

(iv) Information concerning any personal protective equipment and respiratory protection used or to be used by the employee; and

(v) Information from previous medical examinations of the affected employee within the control of the employer.

(vi) In the event of a nonroutine examination because of an emergency, the employer shall provide to the physician as soon as possible: A description of how the emergency occurred and the exposure the victim may have received.

(7) Physician's written opinion.

(i) For each examination required under this standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:

(A) The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;

(B) Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;

(C) A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.

(ii) The employer shall provide for retention of the results of the medical examination and tests conducted by the physician.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

(8) Medical removal.

(i) The provisions of paragraph (l)(8) apply when an employee reports significant irritation of the mucosa of the eyes or the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization attributed to workplace formaldehyde exposure. Medical removal provisions do not apply in the case of dermal irritation or dermal sensitization when the product suspected of causing the dermal condition contains less than 0.05% formaldehyde.

(ii) An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by the employer pursuant to paragraph (l)(3). If the physician determines that a medical examination is not necessary under paragraph (l)(3)(ii), there shall be a two-week evaluation and remediation period to permit the employer to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.

(iii) If the signs or symptoms have not subsided or been remedied by the end of the two-week period, or earlier if signs or symptoms warrant, the employee shall be examined by a physician selected by the employer. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1% formaldehyde.

(iv) Medical examinations shall be conducted in compliance with the requirements of paragraph (l)(5)(i) and (ii). Additional guidelines for conducting medical exams are contained in appendix C.

(v) If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization result from workplace formaldehyde exposure and recommends restrictions or removal, the employer shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, the employer shall remove the effected employee from the current formaldehyde exposure and if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

(vi) When an employee is removed pursuant to paragraph (l)(8)(v), the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the formaldehyde exposures are as low as possible, but not higher than the action level. The employer shall maintain the employee's current

earnings, seniority, and other benefits. If there is no such work available, the employer shall maintain the employee's current earnings, seniority and other benefits until such work becomes available, until the employee is determined to be unable to return to workplace formaldehyde exposure, until the employee is determined to be able to return to the original job status, or for six months, whichever comes first.

(vii) The employer shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status, or if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status, or if the removal is to be permanent.

(viii) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(ix) In making determinations of the formaldehyde content of materials under this paragraph the employer may rely on objective data.

(9) Multiple physician review.

(i) After the employer selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or recommendations of the initial physician and to conduct such examinations, consultations, and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

(ii) The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation for the purpose of medical removal or restriction.

(iii) The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a second medical opinion, or receipt of the initial physician's written opinion, whichever is later;

(A) The employee informs the employer of the intention to seek a second medical opinion, and

(B) The employee initiates steps to make an appointment with a second physician.

(iv) If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

(A) To review the findings, determinations or recommendations of the prior physicians; and

(B) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

(v) In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

(vi) The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

(m) Communication of hazards.

(1) Hazard communication—General.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for formaldehyde.

(ii) In classifying the hazards of formaldehyde at least the following hazards are to be addressed: Cancer; skin and respiratory sensitization; eye, skin and respiratory tract irritation; acute toxicity effects; and flammability.

(iii) Employers shall include formaldehyde in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of formaldehyde and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

(iv) Paragraphs (m)(1)(i), (m)(1)(ii), and (m)(1)(iii) of this section apply to chemicals associated with formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm.

(v) In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

(2)(i) In addition to the requirements in paragraphs (m)(1) through (m)(1)(iv) of this section, for materials listed in paragraph (m)(1)(iv) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in paragraph (d) of § 1910.1200 and Appendices A and B to § 1910.1200, including cancer and respiratory sensitization, and shall contain the hazard statement “May Cause Cancer.”

(ii) As a minimum, for all materials listed in paragraph (m)(1)(i) and (iv) of this section capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address

of the responsible party; and state that physical and health hazard information is readily available from the employer and from safety data sheets.

(iii) Prior to June 1, 2015, employers may include the phrase "Potential Cancer Hazard" in lieu of "May Cause Cancer" as specified in paragraph (m)(2)(i) of this section.

(n) Employee information and training—

(1) Participation. The employer shall assure that all employees who are assigned to workplaces where there is exposure to formaldehyde participate in a training program, except that where the employer can show, using objective data, that employees are not exposed to formaldehyde at or above 0.1 ppm, the employer is not required to provide training.

(2) Frequency. Employers shall provide such information and training to employees at the time of initial assignment, and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

(3) Training program. The training program shall be conducted in a manner which the employee is able to understand and shall include:

(i) A discussion of the contents of this regulation and the contents of the Material Safety Data Sheet.

(ii) The purpose for and a description of the medical surveillance program required by this standard, including:

(A) A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde.

(B) Instructions to immediately report to the employer the development of any adverse signs or symptoms that the employee suspects is attributable to formaldehyde exposure.

(iii) Description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

(iv) The purpose for, proper use of, and limitations of personal protective clothing and equipment;

(v) Instructions for the handling of spills, emergencies, and clean-up procedures;

(vi) An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

(vii) A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

(4) Access to training materials.

(i) The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

(ii) The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.

(o) Recordkeeping—

(1) Exposure measurements. The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

(i) The date of measurement;

(ii) The operation being monitored;

(iii) The methods of sampling and analysis and evidence of their accuracy and precision;

(iv) The number, durations, time, and results of samples taken;

(v) The types of protective devices worn; and

(vi) The names, job classifications, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

(2) Exposure determinations. Where the employer has determined that no monitoring is required under this standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

(3) Medical surveillance. The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this standard. This record shall include:

(i) The name of the employee;

(ii) The physician's written opinion;

(iii) A list of any employee health complaints that may be related to exposure to formaldehyde; and

(iv) A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the standard or mandated by the examining physician.

(4) Respirator fit testing.

(i) The employer shall establish and maintain accurate records for employees subject to negative pressure respirator fit testing required by this standard.

(ii) This record shall include:

(A) A copy of the protocol selected for respirator fit testing.

(B) A copy of the results of any fit testing performed.

(C) The size and manufacturer of the types of respirators available for selection.

(D) The date of the most recent fit testing, the name of each tested employee, and the respirator type and facepiece selected.

(5) Record retention. The employer shall retain records required by this standard for at least the following periods:

(i) Exposure records and determinations shall be kept for at least 30 years.

(ii) Medical records shall be kept for the duration of employment plus 30 years.

(iii) Respirator fit testing records shall be kept until replaced by a more recent record.

(6) Availability of records.

(i) Upon request, the employer shall make all records maintained as a requirement of this standard available for examination and copying to the Assistant Secretary and the Director.

(ii) The employer shall make employee exposure records, including estimates made from representative monitoring and available upon request for examination, and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.1020(a)–(e) and (g)–(i).

(iii) Employee medical records required by this standard shall be provided upon request for examination and copying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.1020(a)–(e) and (g)–(i).

Credits

[52 FR 46291, Dec. 4, 1987; 53 FR 6629, March 2, 1988; 53 FR 45082, Nov. 8, 1988; 53 FR 47188, Nov. 22, 1988; 53 FR 50199, Dec. 13, 1988; 54 FR 24334, June 7, 1989; 54 FR 29546, July 13, 1989; 54 FR 31765, Aug. 1, 1989; 54 FR 35639, Aug. 29, 1989; 55 FR 24070, June 13, 1990; 55 FR 32616, Aug. 10, 1990; 55 FR 51699, Dec. 17, 1990; 56 FR 10378, March 12, 1991; 56 FR 26909, June 12, 1991; 56 FR 37651, Aug. 8, 1991; 56 FR 57593, Nov. 13, 1991; 57 FR 2682, Jan. 23, 1992; 57 FR 19262, May 5, 1992; 57 FR 22307, 22310, May 27, 1992; 57 FR 24701, June 10, 1992; 57 FR 27161, June 18, 1992; 61 FR 5508, Feb. 13, 1996; 63 FR 1292, Jan. 8, 1998; 63 FR 20099, April 23, 1998; 70 FR 1143, Jan. 5, 2005; 71 FR 16672, 16673, April 3, 2006; 71 FR 50190, Aug. 24, 2006; 73 FR 75586, Dec. 12, 2008; 77 FR 17784, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 84 FR 21597, May 14, 2019]

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AUTHORITY: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 08–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2007 (72 FR 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.; All of subpart Z issued under 29 U.S.C. 655(b), except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of § 1910.1000. The latter were issued under 29 U.S.C. 655(a).; Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.; Section 1910.1001 also issued under 40 U.S.C. 3704 and 5 U.S.C. 553.; Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.; Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.; Section 1910.1030 also issued under Public Law 106–430, 114 Stat. 1901.; Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Notes of Decisions (8)

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

Code of Federal Regulations
Title 29. Labor
Subtitle B. Regulations Relating to Labor
Chapter XVII. Occupational Safety and Health Administration, Department of Labor
Part 1910. Occupational Safety and Health Standards (Refs & Annos)
Subpart Z. Toxic and Hazardous Substances (Refs & Annos)

29 C.F.R. § 1910.1052

§ 1910.1052 Methylene Chloride.

Effective: July 15, 2019
Currentness

This occupational health standard establishes requirements for employers to control occupational exposure to methylene chloride (MC). Employees exposed to MC are at increased risk of developing cancer, adverse effects on the heart, central nervous system and liver, and skin or eye irritation. Exposure may occur through inhalation, by absorption through the skin, or through contact with the skin. MC is a solvent which is used in many different types of work activities, such as paint stripping, polyurethane foam manufacturing, and cleaning and degreasing. Under the requirements of paragraph (d) of this section, each covered employer must make an initial determination of each employee's exposure to MC. If the employer determines that employees are exposed below the action level, the only other provisions of this section that apply are that a record must be made of the determination, the employees must receive information and training under paragraph (l) of this section and, where appropriate, employees must be protected from contact with liquid MC under paragraph (h) of this section. The provisions of the MC standard are as follows:

(a) Scope and application. This section applies to all occupational exposures to methylene chloride (MC), Chemical Abstracts Service Registry Number 75–09–2, in general industry, construction and shipyard employment.

(b) Definitions. For the purposes of this section, the following definitions shall apply:

Action level means a concentration of airborne MC of 12.5 parts per million (ppm) calculated as an eight (8)–hour time-weighted average (TWA).

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer and required by work duties to be present in regulated areas, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (d) of this section, or any other person authorized by the OSH Act or regulations issued under the Act.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence, such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which results, or is likely to result in an uncontrolled release of MC. If an incidental release of MC can be controlled

by employees such as maintenance personnel at the time of release and in accordance with the leak/spill provisions required by paragraph (f) of this section, it is not considered an emergency as defined by this standard.

Employee exposure means exposure to airborne MC which occurs or would occur if the employee were not using respiratory protection.

Methylene chloride (MC) means an organic compound with chemical formula, CH_2Cl_2. Its Chemical Abstracts Service Registry Number is 75–09–2. Its molecular weight is 84.9 g/mole.

Physician or other licensed health care professional is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (j) of this section.

Regulated area means an area, demarcated by the employer, where an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed either the 8–hour TWA PEL or the STEL.

Symptom means central nervous system effects such as headaches, disorientation, dizziness, fatigue, and decreased attention span; skin effects such as chapping, erythema, cracked skin, or skin burns; and cardiac effects such as chest pain or shortness of breath.

This section means this methylene chloride standard.

(c) Permissible exposure limits (PELs)—

(1) Eight-hour time-weighted average (TWA) PEL. The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of twenty-five parts of MC per million parts of air (25 ppm) as an 8–hour TWA.

(2) Short-term exposure limit (STEL). The employer shall ensure that no employee is exposed to an airborne concentration of MC in excess of one hundred and twenty-five parts of MC per million parts of air (125 ppm) as determined over a sampling period of fifteen minutes.

(d) Exposure monitoring—

(1) Characterization of employee exposure.

(i) Where MC is present in the workplace, the employer shall determine each employee's exposure by either:

(A) Taking a personal breathing zone air sample of each employee's exposure; or

(B) Taking personal breathing zone air samples that are representative of each employee's exposure.

(ii) Representative samples. The employer may consider personal breathing zone air samples to be representative of employee exposures when they are taken as follows:

(A) 8–hour TWA PEL. The employer has taken one or more personal breathing zone air samples for at least one employee in each job classification in a work area during every work shift, and the employee sampled is expected to have the highest MC exposure.

(B) Short-term exposure limits. The employer has taken one or more personal breathing zone air samples which indicate the highest likely 15–minute exposures during such operations for at least one employee in each job classification in the work area during every work shift, and the employee sampled is expected to have the highest MC exposure.

(C) Exception. Personal breathing zone air samples taken during one work shift may be used to represent employee exposures on other work shifts where the employer can document that the tasks performed and conditions in the workplace are similar across shifts.

(iii) Accuracy of monitoring. The employer shall ensure that the methods used to perform exposure monitoring produce results that are accurate to a confidence level of 95 percent, and are:

(A) Within plus or minus 25 percent for airborne concentrations of MC above the 8–hour TWA PEL or the STEL; or

(B) Within plus or minus 35 percent for airborne concentrations of MC at or above the action level but at or below the 8–hour TWA PEL.

(2) Initial determination. Each employer whose employees are exposed to MC shall perform initial exposure monitoring to determine each affected employee's exposure, except under the following conditions:

(i) Where objective data demonstrate that MC cannot be released in the workplace in airborne concentrations at or above the action level or above the STEL. The objective data shall represent the highest MC exposures likely to occur under reasonably foreseeable conditions of processing, use, or handling. The employer shall document the objective data exemption as specified in paragraph (m) of this section;

(ii) Where the employer has performed exposure monitoring within 12 months prior to April 10, 1997 and that exposure monitoring meets all other requirements of this section, and was conducted under conditions substantially equivalent to existing conditions; or

(iii) Where employees are exposed to MC on fewer than 30 days per year (e.g., on a construction site), and the employer has measurements by direct-reading instruments which give immediate results (such as a detector tube) and which provide sufficient information regarding employee exposures to determine what control measures are necessary to reduce exposures to acceptable levels.

(3) Periodic monitoring. Where the initial determination shows employee exposures at or above the action level or above the STEL, the employer shall establish an exposure monitoring program for periodic monitoring of employee exposure to MC in accordance with Table 1:

Table 1—Initial Determination Exposure Scenarios and Their Associated Monitoring Frequencies

Exposure scenario	Required monitoring activity
Below the action level and at or below the STEL	No 8-hour TWA or STEL monitoring required.
Below the action level and above the STEL	No 8-hour TWA monitoring required; monitor STEL exposures every three months.
At or above the action level, at or below the TWA, and at or below the STEL	Monitor 8-hour TWA exposures every six months.
At or above the action level, at or below the TWA, and above the STEL	Monitor 8-hour TWA exposures every six months and monitor STEL exposures every three months.
Above the TWA and at or below the STEL	Monitor 8-hour TWA exposures every three months. In addition, without regard to the last sentence of the note to paragraph (d)(3), the following employers must monitor STEL exposures every three months until either the date by which they must achieve the 8-hour TWA PEL under paragraph (n) of this section or the date by which they in fact achieve the 8-hour TWA PEL, whichever comes first: employers engaged in polyurethane foam manufacturing; foam fabrication; furniture refinishing; general aviation aircraft stripping; product formulation; use of MC-based adhesives for boat building and repair, recreational vehicle manufacture, van conversion, or upholstery; and use of MC in construction work for restoration and preservation of buildings, painting and paint removal, cabinet making, or floor refinishing and resurfacing.
Above the TWA and above the STEL	Monitor 8-hour TWA exposures and STEL exposures every three months.

[Note to paragraph (d)(3): The employer may decrease the frequency of 8–hour TWA exposure monitoring to every six months when at least two consecutive measurements taken at least seven days apart show exposures to be at or below the 8–hour TWA PEL. The employer may discontinue the periodic 8–hour TWA monitoring for employees where at least two consecutive measurements taken at least seven days apart are below the action level. The employer may discontinue the periodic STEL monitoring for employees where at least two consecutive measurements taken at least 7 days apart are at or below the STEL.]

(4) Additional monitoring.

(i) The employer shall perform exposure monitoring when a change in workplace conditions indicates that employee exposure may have increased. Examples of situations that may require additional monitoring include changes in production, process, control equipment, or work practices, or a leak, rupture, or other breakdown.

(ii) Where exposure monitoring is performed due to a spill, leak, rupture or equipment breakdown, the employer shall clean-up the MC and perform the appropriate repairs before monitoring.

(5) Employee notification of monitoring results.

(i) The employer shall, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results in writing, either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) Whenever monitoring results indicate that employee exposure is above the 8–hour TWA PEL or the STEL, the employer shall describe in the written notification the corrective action being taken to reduce employee exposure to or below the 8–hour TWA PEL or STEL and the schedule for completion of this action.

(6) Observation of monitoring—

(i) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to MC conducted in accordance with this section.

(ii) Observation procedures. When observation of the monitoring of employee exposure to MC requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide, at no cost to the observer(s), and the observer(s) shall be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(e) Regulated areas.

(1) The employer shall establish a regulated area wherever an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed either the 8–hour TWA PEL or the STEL.

(2) The employer shall limit access to regulated areas to authorized persons.

(3) The employer shall supply a respirator, selected in accordance with paragraph (h)(3) of this section, to each person who enters a regulated area and shall require each affected employee to use that respirator whenever MC exposures are likely to exceed the 8–hour TWA PEL or STEL.

[Note to paragraph (e)(3): An employer who has implemented all feasible engineering, work practice and administrative controls (as required in paragraph (f) of this section), and who has established a regulated area (as required by paragraph (e)(1) of this section) where MC exposure can be reliably predicted to exceed the 8–hour TWA PEL or the STEL only on certain days (for example, because of work or process schedule) would need to have affected employees use respirators in that regulated area only on those days.]

(4) The employer shall ensure that, within a regulated area, employees do not engage in non-work activities which may increase dermal or oral MC exposure.

(5) The employer shall ensure that while employees are wearing respirators, they do not engage in activities (such as taking medication or chewing gum or tobacco) which interfere with respirator seal or performance.

(6) The employer shall demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts employees to the boundaries of the area and minimizes the number of authorized employees exposed to MC within the regulated area.

(7) An employer at a multi-employer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to all other employers with work operations at that worksite.

(f) Methods of compliance—

(1) Engineering and work practice controls. The employer shall institute and maintain the effectiveness of engineering controls and work practices to reduce employee exposure to or below the PELs except to the extent that the employer can demonstrate that such controls are not feasible. Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the 8–TWA PEL or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(2) Prohibition of rotation. The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(3) Leak and spill detection.

(i) The employer shall implement procedures to detect leaks of MC in the workplace. In work areas where spills may occur, the employer shall make provisions to contain any spills and to safely dispose of any MC-contaminated waste materials.

(ii) The employer shall ensure that all incidental leaks are repaired and that incidental spills are cleaned promptly by employees who use the appropriate personal protective equipment and are trained in proper methods of cleanup.

[Note to paragraph (f)(3)(ii): See appendix A of this section for examples of procedures that satisfy this requirement. Employers covered by this standard may also be subject to the hazardous waste and emergency response provisions contained in 29 CFR 1910.120 (q).]

(g) Respiratory protection—

(1) General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

(i) Periods when an employee's exposure to MC exceeds the 8–hour TWA PEL, or STEL (for example, when an employee is using MC in a regulated area).

(ii) Periods necessary to install or implement feasible engineering and work-practice controls.

(iii) A few work operations, such as some maintenance operations and repair activities, for which the employer demonstrates that engineering and work-practice controls are infeasible.

(iv) Work operations for which feasible engineering and work-practice controls are not sufficient to reduce employee exposures to or below the PELs.

(v) Emergencies.

(2) Respirator program.

(i) The employer must implement a respiratory protection program in accordance with § 1910.13(b) through (m) (except (d)(1)(iii)), which covers each employee required by this section to use a respirator.

(ii) Employers who provide employees with gas masks with organic-vapor canisters for the purpose of emergency escape must replace the canisters after any emergency use and before the gas masks are returned to service.

(3) Respirator selection. Employers must:

(i) Select, and provide to employees, the appropriate atmosphere-supplying respirator specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half masks of any type because MC may cause eye irritation or damage.

(ii) For emergency escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the continuous-flow or pressure-demand mode; or a gas mask with an organic vapor canister.

(4) Medical evaluation. Before having an employee use a supplied-air respirator in the negative-pressure mode, or a gas mask with an organic-vapor canister for emergency escape, the employer must:

(i) Have a physician or other licensed health-care professional (PLHCP) evaluate the employee's ability to use such respiratory protection.

(ii) Ensure that the PLHCP provides their findings in a written opinion to the employee and the employer.

(h) Protective Work Clothing and Equipment.

(1) Where needed to prevent MC-induced skin or eye irritation, the employer shall provide clean protective clothing and equipment which is resistant to MC, at no cost to the employee, and shall ensure that each affected employee uses it. Eye and face protection shall meet the requirements of 29 CFR 1910.133 or 29 CFR 1915.153, as applicable.

(2) The employer shall clean, launder, repair and replace all protective clothing and equipment required by this paragraph as needed to maintain their effectiveness.

(3) The employer shall be responsible for the safe disposal of such clothing and equipment.

[Note to paragraph (h)(4): See appendix A for examples of disposal procedures that will satisfy this requirement.]

(i) Hygiene facilities.

(1) If it is reasonably foreseeable that employees' skin may contact solutions containing 0.1 percent or greater MC (for example, through splashes, spills or improper work practices), the employer shall provide conveniently located washing facilities capable of removing the MC, and shall ensure that affected employees use these facilities as needed.

(2) If it is reasonably foreseeable that an employee's eyes may contact solutions containing 0.1 percent or greater MC (for example through splashes, spills or improper work practices), the employer shall provide appropriate eyewash facilities within the immediate work area for emergency use, and shall ensure that affected employees use those facilities when necessary.

(j) Medical surveillance—

(1) Affected employees. The employer shall make medical surveillance available for employees who are or may be exposed to MC as follows:

(i) At or above the action level on 30 or more days per year, or above the 8–hour TWA PEL or the STEL on 10 or more days per year;

(ii) Above the 8–TWA PEL or STEL for any time period where an employee has been identified by a physician or other licensed health care professional as being at risk from cardiac disease or from some other serious MC-related health condition and such employee requests inclusion in the medical surveillance program;

(iii) During an emergency.

(2) Costs. The employer shall provide all required medical surveillance at no cost to affected employees, without loss of pay and at a reasonable time and place.

(3) Medical personnel. The employer shall ensure that all medical surveillance procedures are performed by a physician or other licensed health care professional, as defined in paragraph (b) of this section.

(4) Frequency of medical surveillance. The employer shall make medical surveillance available to each affected employee as follows:

(i) Initial surveillance. The employer shall provide initial medical surveillance under the schedule provided by paragraph (n)(2)(iii) of this section, or before the time of initial assignment of the employee, whichever is later. The employer need not provide the initial surveillance if medical records show that an affected employee has been provided with medical surveillance that complies with this section within 12 months before April 10, 1997.

(ii) Periodic medical surveillance. The employer shall update the medical and work history for each affected employee annually. The employer shall provide periodic physical examinations, including appropriate laboratory surveillance, as follows:

(A) For employees 45 years of age or older, within 12 months of the initial surveillance or any subsequent medical surveillance; and

(B) For employees younger than 45 years of age, within 36 months of the initial surveillance or any subsequent medical surveillance.

(iii) Termination of employment or reassignment. When an employee leaves the employer's workplace, or is reassigned to an area where exposure to MC is consistently at or below the action level and STEL, medical surveillance shall be made available if six months or more have elapsed since the last medical surveillance.

(iv) Additional surveillance. The employer shall provide additional medical surveillance at frequencies other than those listed above when recommended in the written medical opinion. (For example, the physician or other licensed health care professional may determine an examination is warranted in less than 36 months for employees younger than 45 years of age based upon evaluation of the results of the annual medical and work history.)

(5) Content of medical surveillance—

(i) Medical and work history. The comprehensive medical and work history shall emphasize neurological symptoms, skin conditions, history of hematologic or liver disease, signs or symptoms suggestive of heart disease (angina, coronary artery disease), risk factors for cardiac disease, MC exposures, and work practices and personal protective equipment used during such exposures.

[Note to paragraph (j)(5)(i): See appendix B of this section for an example of a medical and work history format that would satisfy this requirement.]

(ii) Physical examination. Where physical examinations are provided as required above, the physician or other licensed health care professional shall accord particular attention to the lungs, cardiovascular system (including blood pressure and pulse), liver, nervous system, and skin. The physician or other licensed health care professional shall determine the extent and nature of the physical examination based on the health status of the employee and analysis of the medical and work history.

(iii) Laboratory surveillance. The physician or other licensed health care professional shall determine the extent of any required laboratory surveillance based on the employee's observed health status and the medical and work history.

[Note to paragraph (j)(5)(iii): See appendix B of this section for information regarding medical tests. Laboratory surveillance may include before- and after-shift carboxyhemoglobin determinations, resting ECG, hematocrit, liver function tests and cholesterol levels.]

(iv) Other information or reports. The medical surveillance shall also include any other information or reports the physician or other licensed health care professional determines are necessary to assess the employee's health in relation to MC exposure.

(6) Content of emergency medical surveillance. The employer shall ensure that medical surveillance made available when an employee has been exposed to MC in emergency situations includes, at a minimum:

(i) Appropriate emergency treatment and decontamination of the exposed employee;

(ii) Comprehensive physical examination with special emphasis on the nervous system, cardiovascular system, lungs, liver and skin, including blood pressure and pulse;

(iii) Updated medical and work history, as appropriate for the medical condition of the employee; and

(iv) Laboratory surveillance, as indicated by the employee's health status.

[Note to paragraph (j)(6)(iv): See appendix B for examples of tests which may be appropriate.]

(7) Additional examinations and referrals. Where the physician or other licensed health care professional determines it is necessary, the scope of the medical examination shall be expanded and the appropriate additional medical surveillance, such as referrals for consultation or examination, shall be provided.

(8) Information provided to the physician or other licensed health care professional. The employer shall provide the following information to a physician or other licensed health care professional who is involved in the diagnosis of MC-induced health effects:

(i) A copy of this section including its applicable appendices;

(ii) A description of the affected employee's past, current and anticipated future duties as they relate to the employee's MC exposure;

(iii) The employee's former or current exposure levels or, for employees not yet occupationally exposed to MC, the employee's anticipated exposure levels and the frequency and exposure levels anticipated to be associated with emergencies;

(iv) A description of any personal protective equipment, such as respirators, used or to be used; and

(v) Information from previous employment-related medical surveillance of the affected employee which is not otherwise available to the physician or other licensed health care professional.

(9) Written medical opinions.

(i) For each physical examination required by this section, the employer shall ensure that the physician or other licensed health care professional provides to the employer and to the affected employee a written opinion regarding the results of that examination within 15 days of completion of the evaluation of medical and laboratory findings, but not more than 30 days after the examination. The written medical opinion shall be limited to the following information:

(A) The physician or other licensed health care professional's opinion concerning whether exposure to MC may contribute to or aggravate the employee's existing cardiac, hepatic, neurological (including stroke) or dermal disease or whether the employee has any other medical condition(s) that would place the employee's health at increased risk of material impairment from exposure to MC.

(B) Any recommended limitations upon the employee's exposure to MC, including removal from MC exposure, or upon the employee's use of respirators, protective clothing, or other protective equipment.

(C) A statement that the employee has been informed by the physician or other licensed health care professional that MC is a potential occupational carcinogen, of risk factors for heart disease, and the potential for exacerbation of underlying heart disease by exposure to MC through its metabolism to carbon monoxide; and

(D) A statement that the employee has been informed by the physician or other licensed health care professional of the results of the medical examination and any medical conditions resulting from MC exposure which require further explanation or treatment.

(ii) The employer shall instruct the physician or other licensed health care professional not to reveal to the employer, orally or in the written opinion, any specific records, findings, and diagnoses that have no bearing on occupational exposure to MC.

[Note to paragraph (j)(9)(ii): The written medical opinion may also include information and opinions generated to comply with other OSHA health standards.]

(10) Medical presumption. For purposes of this paragraph (j) of this section, the physician or other licensed health care professional shall presume, unless medical evidence indicates to the contrary, that a medical condition is unlikely to require medical removal from MC exposure if the employee is not exposed to MC above the 8–hour TWA PEL. If the physician or other licensed health care professional recommends removal for an employee exposed below the 8–hour TWA PEL, the physician or other licensed health care professional shall cite specific medical evidence, sufficient to rebut the presumption that exposure below the 8–hour TWA PEL is unlikely to require removal, to support the recommendation. If such evidence is cited by the physician or other licensed health care professional, the employer must remove the employee. If such evidence is not cited by the physician or other licensed health care professional, the employer is not required to remove the employee.

(11) Medical Removal Protection (MRP).

(i) Temporary medical removal and return of an employee.

(A) Except as provided in paragraph (j)(10) of this section, when a medical determination recommends removal because the employee's exposure to MC may contribute to or aggravate the employee's existing cardiac, hepatic, neurological (including stroke), or skin disease, the employer must provide medical removal protection benefits to the employee and either:

(1) Transfer the employee to comparable work where methylene chloride exposure is below the action level; or

(2) Remove the employee from MC exposure.

(B) If comparable work is not available and the employer is able to demonstrate that removal and the costs of extending MRP benefits to an additional employee, considering feasibility in relation to the size of the employer's business and the other requirements of this standard, make further reliance on MRP an inappropriate remedy, the employer may retain the additional employee in the existing job until transfer or removal becomes appropriate, provided:

(1) The employer ensures that the employee receives additional medical surveillance, including a physical examination at least every 60 days until transfer or removal occurs; and

(2) The employer or PLHCP informs the employee of the risk to the employee's health from continued MC exposure.

(C) The employer shall maintain in effect any job-related protective measures or limitations, other than removal, for as long as a medical determination recommends them to be necessary.

(ii) End of MRP benefits and return of the employee to former job status.

(A) The employer may cease providing MRP benefits at the earliest of the following:

(1) Six months;

(2) Return of the employee to the employee's former job status following receipt of a medical determination concluding that the employee's exposure to MC no longer will aggravate any cardiac, hepatic, neurological (including stroke), or dermal disease;

(3) Receipt of a medical determination concluding that the employee can never return to MC exposure.

(B) For the purposes of this paragraph (j), the requirement that an employer return an employee to the employee's former job status is not intended to expand upon or restrict any rights an employee has or would have had, absent temporary medical removal, to a specific job classification or position under the terms of a collective bargaining agreement.

(12) Medical removal protection benefits.

(i) For purposes of this paragraph (j), the term medical removal protection benefits means that, for each removal, an employer must maintain for up to six months the earnings, seniority, and other employment rights and benefits of the employee as though the employee had not been removed from MC exposure or transferred to a comparable job.

(ii) During the period of time that an employee is removed from exposure to MC, the employer may condition the provision of medical removal protection benefits upon the employee's participation in follow-up medical surveillance made available pursuant to this section.

(iii) If a removed employee files a workers' compensation claim for a MC–related disability, the employer shall continue the MRP benefits required by this paragraph until either the claim is resolved or the 6–month period for payment of MRP benefits has passed, whichever occurs first. To the extent the employee is entitled to indemnity payments for earnings lost during the period of removal, the employer's obligation to provide medical removal protection benefits to the employee shall be reduced by the amount of such indemnity payments.

(iv) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from either a publicly or an employer-funded compensation program, or receives income from employment with another employer made possible by virtue of the employee's removal.

(13) Voluntary removal or restriction of an employee. Where an employer, although not required by this section to do so, removes an employee from exposure to MC or otherwise places any limitation on an employee due to the effects of MC exposure on the employee's medical condition, the employer shall provide medical removal protection benefits to the employee equal to those required by paragraph (j)(12) of this section.

(14) Multiple health care professional review mechanism.

(i) If the employer selects the initial physician or licensed health care professional (PLHCP) to conduct any medical examination or consultation provided to an employee under this paragraph (j)(11), the employer shall notify the employee of the right to seek a second medical opinion each time the employer provides the employee with a copy of the written opinion of that PLHCP.

(ii) If the employee does not agree with the opinion of the employer-selected PLHCP, notifies the employer of that fact, and takes steps to make an appointment with a second PLHCP within 15 days of receiving a copy of the written opinion of the initial PLHCP, the employer shall pay for the PLHCP chosen by the employee to perform at least the following:

(A) Review any findings, determinations or recommendations of the initial PLHCP; and

(B) Conduct such examinations, consultations, and laboratory tests as the PLHCP deems necessary to facilitate this review.

(iii) If the findings, determinations or recommendations of the second PLHCP differ from those of the initial PLHCP, then the employer and the employee shall instruct the two health care professionals to resolve the disagreement.

(iv) If the two health care professionals are unable to resolve their disagreement within 15 days, then those two health care professionals shall jointly designate a PLHCP who is a specialist in the field at issue. The employer shall pay for the specialist to perform at least the following:

(A) Review the findings, determinations, and recommendations of the first two PLHCPs; and

(B) Conduct such examinations, consultations, laboratory tests and discussions with the prior PLHCPs as the specialist deems necessary to resolve the disagreements of the prior health care professionals.

(v) The written opinion of the specialist shall be the definitive medical determination. The employer shall act consistent with the definitive medical determination, unless the employer and employee agree that the written opinion of one of the other two PLHCPs shall be the definitive medical determination.

(vi) The employer and the employee or authorized employee representative may agree upon the use of any expeditious alternate health care professional determination mechanism in lieu of the multiple health care professional review mechanism provided by this paragraph so long as the alternate mechanism otherwise satisfies the requirements contained in this paragraph.

(k) Hazard communication.—

(1) Hazard communication—general.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for MC.

(ii) In classifying the hazards of MC at least the following hazards are to be addressed: Cancer, cardiac effects (including elevation of carboxyhemoglobin), central nervous system effects, liver effects, and skin and eye irritation.

(iii) Employers shall include MC in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of MC and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l) of this section.

(2) [Reserved]

(l) Employee information and training.

(1) The employer shall provide information and training for each affected employee prior to or at the time of initial assignment to a job involving potential exposure to MC.

(2) The employer shall ensure that information and training is presented in a manner that is understandable to the employees.

(3) In addition to the information required under the Hazard Communication Standard at 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate:

(i) The employer shall inform each affected employee of the requirements of this section and information available in its appendices, as well as how to access or obtain a copy of it in the workplace;

(ii) Wherever an employee's exposure to airborne concentrations of MC exceeds or can reasonably be expected to exceed the action level, the employer shall inform each affected employee of the quantity, location, manner of use, release, and storage of MC and the specific operations in the workplace that could result in exposure to MC, particularly noting where exposures may be above the 8–hour TWA PEL or STEL;

(4) The employer shall train each affected employee as required under the Hazard Communication standard at 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate.

(5) The employer shall re-train each affected employee as necessary to ensure that each employee exposed above the action level or the STEL maintains the requisite understanding of the principles of safe use and handling of MC in the workplace.

(6) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, which increase employee exposure, and where those exposures exceed or can reasonably be expected to exceed the action level, the employer shall update the training as necessary to ensure that each affected employee has the requisite proficiency.

(7) An employer whose employees are exposed to MC at a multi-employer worksite shall notify the other employers with work operations at that site in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, or 29 CFR 1926.59, as appropriate.

(8) The employer shall provide to the Assistant Secretary or the Director, upon request, all available materials relating to employee information and training.

(m) Recordkeeping—

(1) Objective data.

(i) Where an employer seeks to demonstrate that initial monitoring is unnecessary through reasonable reliance on objective data showing that any materials in the workplace containing MC will not release MC at levels which exceed the action level or the STEL under foreseeable conditions of exposure, the employer shall establish and maintain an accurate record of the objective data relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The MC-containing material in question;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of MC;

(D) A description of the operation exempted under paragraph (d)(2)(i) of this section and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) Exposure measurements.

(i) The employer shall establish and keep an accurate record of all measurements taken to monitor employee exposure to MC as prescribed in paragraph (d) of this section.

(ii) Where the employer has 20 or more employees, this record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) The operation involving exposure to MC which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of personal protective equipment, such as respiratory protective devices, worn, if any; and

(F) Name, job classification and exposure of all of the employees represented by monitoring, indicating which employees were actually monitored.

(iii) Where the employer has fewer than 20 employees, the record shall include at least the following information:

(A) The date of measurement for each sample taken;

(B) Number, duration, and results of samples taken; and

(C) Name, job classification and exposure of all of the employees represented by monitoring, indicating which employees were actually monitored.

(iv) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

(3) Medical surveillance.

(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under paragraph (j) of this section.

(ii) The record shall include at least the following information:

(A) The name and description of the duties of the employee;

(B) Written medical opinions; and

(C) Any employee medical conditions related to exposure to MC.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

(4) Availability.

(i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying in accordance with 29 CFR 1910.1020.

[Note to paragraph (m)(4)(i): All records required to be maintained by this section may be kept in the most administratively convenient form (for example, electronic or computer records would satisfy this requirement).]

(ii) The employer, upon request, shall make any employee exposure and objective data records required by this section available for examination and copying by affected employees, former employees, and designated representatives in accordance with 29 CFR 1910.1020.

(iii) The employer, upon request, shall make employee medical records required to be kept by this section available for examination and copying by the subject employee and by anyone having the specific written consent of the subject employee in accordance with 29 CFR 1910.1020.

(5) Transfer of records. The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

(n) [Reserved]

(o) Appendices. The information contained in the appendices does not, by itself, create any additional obligations not otherwise imposed or detract from any existing obligation.

[Note to paragraph (o): The requirement of 29 CFR 1910.1052(g)(1) to use respiratory protection whenever an employee's exposure to methylene chloride exceeds or can reasonably be expected to exceed the 8–hour TWA PEL is hereby stayed until August 31, 1998 for employers engaged in polyurethane foam manufacturing; foam fabrication; furniture refinishing; general aviation aircraft stripping; formulation of products containing methylene chloride; boat building and repair; recreational vehicle manufacture; van conversion; upholstery; and use of methylene chloride in construction work for restoration and preservation of buildings, painting and paint removal, cabinet making and/or floor refinishing and resurfacing.

The requirement of 29 CFR 1910.1052(f)(1) to implement engineering controls to achieve the 8–hour TWA PEL and STEL is hereby stayed until December 10, 1998 for employers with more than 100 employees engaged in polyurethane foam manufacturing and for employers with more than 20 employees engaged in foam fabrication; furniture refinishing; general aviation aircraft stripping; formulation of products containing methylene chloride; boat building and repair; recreational vehicle manufacture; van conversion; upholstery; and use of methylene chloride in construction work for restoration and preservation of buildings, painting and paint removal, cabinet making and/or floor refinishing and resurfacing.]

Credits

[62 FR 1601, Jan. 10, 1997; 62 FR 42666, 42667, Aug. 8, 1997; 62 FR 48176, Sept. 15, 1997; 62 FR 54383, Oct. 20, 1997; 62 FR 66277, Dec. 18, 1997; 63 FR 1295, Jan. 8, 1998; 63 FR 20099, April 23, 1998; 63 FR 50729, Sept. 22, 1998; 71 FR 16674, April 3, 2006; 71 FR 50190, Aug. 24, 2006; 73 FR 75587, Dec. 12, 2008; 77 FR 17785, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 84 FR 21597, May 14, 2019]

SOURCE: 39 FR 23502, June 27, 1974; 40 FR 23073, May 28, 1975; 50 FR 37353, Sept. 13, 1985; 50 FR 48758, Nov. 27, 1985; 51 FR 22733, June 20, 1986; 51 FR 24527, July 7, 1986; 51 FR 34597, Sept. 30, 1986; 52 FR 34562, Sept. 11, 1987; 52 FR 46291, Dec. 4, 1987; 54 FR 2920, Jan. 19, 1989; 54 FR 28059, July 5, 1989; 55 FR 3166, Jan. 30, 1990; 55 FR 3327, Jan. 31, 1990; 55 FR 5118, Feb. 13, 1990; 55 FR 12819, April 6, 1990; 56 FR 64175, Dec. 6, 1991; 58 FR 21780, April 23, 1993; 58 FR 35340, June 30, 1993; 59 FR 36699, July 19, 1994; 60 FR 9624, Feb. 21, 1995; 60 FR 33344, June 28, 1995; 61 FR 9242, March 7, 1996; 61 FR 31430, June 20, 1996; 62 FR 42666, Aug. 8, 1997; 63 FR 1285, Jan. 8, 1998; 63 FR 33467, June 18, 1998; 65 FR 76567, Dec. 7, 2000; 66 FR 5324, Jan. 18, 2001; 66 FR 18191, April 6, 2001; 67 FR 67965, Nov. 7, 2002; 70 FR 1141, Jan. 5, 2005; 71 FR 10373, Feb. 28, 2006; 71 FR 16673, April 3, 2006; 71 FR 50188, Aug. 24, 2006; 73 FR 75584, Dec. 12, 2008; 75 FR 12685, March 17, 2010; 76 FR 33607, June 8, 2011; 77 FR 17778, March 26, 2012; 77 FR 19934, April 3, 2012; 79 FR 21848, April 18, 2014; 81 FR 16861, March 25, 2016; 82 FR 2735, Jan. 9, 2017; 83 FR 39360, Aug. 9, 2018; 84 FR 21458, May 14, 2019; 89 FR 81830, Oct. 9, 2024, unless otherwise noted.

AUTHORITY: 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 08–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), or 5–2007 (72 FR 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.; All of subpart Z issued under 29 U.S.C. 655(b), except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of § 1910.1000. The latter were issued under 29 U.S.C. 655(a).; Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.; Section 1910.1001 also issued under 40 U.S.C. 3704 and 5 U.S.C. 553.; Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.; Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.; Section 1910.1030 also issued under Public Law 106–430, 114 Stat. 1901.; Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

End of Document

40 C.F.R. § 751.109

§ 751.109 Workplace Chemical Protection Program.

Effective: July 8, 2024
Currentness

(a) Applicability. The provisions of this section apply to the following conditions of use of methylene chloride, including manufacturing and processing for export, except to the extent the conditions of use are prohibited by §§ 751.105 and 751.107:

(1) Manufacturing (domestic manufacture);

(2) Manufacturing (import);

(3) Processing: as a reactant;

(4) Processing: incorporation into a formulation, mixture, or reaction product;

(5) Processing: repackaging;

(6) Processing: recycling;

(7) Industrial and commercial use as a laboratory chemical;

(8) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft;

(9) Industrial or commercial use as a bonding agent for solvent welding;

(10) Industrial and commercial use as a processing aid;

(11) Industrial and commercial use for plastic and rubber products manufacturing;

(12) Industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed; and

(13) Disposal.

(b) Relationship to other regulations. For purposes of this section:

(1) Any provisions applying to "employee" in 29 CFR 1910.132, 1910.134, and 1910.1052 also apply equally to potentially exposed persons; and

(2) Any provisions applying to "employer" in 29 CFR 1910.132, 1910.134, and 1910.1052 also apply equally to any owner or operator for the regulated area.

(c) Exposure limits—

(1) ECEL. The owner or operator must ensure that no person is exposed to an airborne concentration of methylene chloride in excess of 2 parts of methylene chloride per million parts of air (2 ppm) as an 8–hour TWA after February 8, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, August 1, 2025 for other owners and operators, or beginning 4 months after introduction of methylene chloride into the workplace if methylene chloride use commences after May 5, 2025, consistent with paragraphs (d) through (f) of this section.

(2) EPA STEL. The owner or operator must ensure that no person is exposed to an airborne concentration of methylene chloride in excess of 16 parts of methylene chloride per million parts of air (16 ppm) as determined over a sampling period of 15 minutes after February 8, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, August 1, 2025 for other owners and operators, or beginning 4 months after introduction of methylene chloride into the workplace if methylene chloride use commences after May 5, 2025, consistent with paragraphs (d) through (f) of this section.

(3) Regulated areas. The owner or operator must:

(i) Establish and maintain regulated areas in accordance with 29 CFR 1910.1052(e)(2) and (4) through (7) by February 8, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, August 1, 2025 for other owners and operators, or within 3 months after receipt of the results of any monitoring data consistent with paragraph (d) of this section.

(ii) Establish a regulated area wherever a potentially exposed person's exposure to airborne concentrations of methylene chloride exceeds or can reasonably be expected to exceed either the ECEL or EPA STEL.

(iii) Demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts potentially exposed persons to the boundaries of the area and minimizes the number of authorized persons exposed to methylene chloride within the regulated area.

(iv) Restrict access to the regulated area by any potentially exposed person who lacks proper training, personal protective equipment, or is otherwise unauthorized to enter.

(d) Exposure monitoring—

(1) In general—

(i) Characterization of exposures. Owners or operators must determine each potentially exposed person's exposure, without regard to respiratory protection, by either:

(A) Taking a personal breathing zone air sample of each potentially exposed person's exposure; or

(B) Taking personal breathing zone air samples that are representative of each potentially exposed person's exposure.

(ii) Representative samples. Owners or operators are permitted to consider personal breathing zone air samples to be representative of each potentially exposed person's exposure, without regard to respiratory protection, when they are taken as follows:

(A) ECEL. The owner or operator has taken one or more personal breathing zone air samples for at least one potentially exposed person in each job classification in a work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure.

(B) EPA STEL. The owner or operator has taken one or more personal breathing zone air samples which indicate the highest likely 15–minute exposures during such operations for at least one potentially exposed person in each job classification in the work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure.

(C) Exception. Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in the workplace are similar across shifts.

(iii) Accuracy of monitoring. Owners or operators must ensure that the methods used to perform exposure monitoring produce results that are accurate to a confidence level of 95%, and are:

(A) Within plus or minus 25% for airborne concentrations of methylene chloride above the ECEL or the EPA STEL; or

(B) Within plus or minus 35% for airborne concentrations of methylene chloride at or above the ECEL action level but at or below the ECEL.

(iv) Currency of monitoring data. Owners or operators are not permitted to rely on monitoring data that is more than 5 years old to demonstrate compliance with initial or periodic monitoring requirements for either the ECEL or the EPA STEL.

(2) Initial monitoring. By November 9, 2026 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, by May 5, 2025 for other owners and operators, or within 30 days of introduction of methylene chloride into the workplace, whichever is later, each owner or operator covered by this section must perform an initial exposure monitoring to determine each potentially exposed person's exposure, unless:

(i) An owner or operator has objective data generated within the last 5 years prior to May 8, 2024 that demonstrates to EPA that methylene chloride cannot be released in the workplace in airborne concentrations at or above the ECEL action level (1–ppm 8–hour TWA) or above the EPA STEL (16 ppm 15–minute TWA) and that the data represents the highest methylene chloride exposures likely to occur under conditions of use described in paragraph (a) of this section; or

(ii) Where potentially exposed persons are exposed to methylene chloride for fewer than 30 days per year, and the owner or operator has measurements by direct-metering devices which give immediate results and which provide sufficient information regarding exposures to determine and implement the control measures that are necessary to reduce exposures to below the ECEL action level and EPA STEL.

(3) Periodic monitoring. The owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to methylene chloride in accordance with table 1.

Table 1 to Paragraph (d)(3)—Periodic Monitoring Requirements Based on Initial Exposure Monitoring Results

Air concentration condition observed during initial exposure monitoring	Periodic monitoring requirement
If the initial exposure monitoring concentration is below the ECEL action level and at or below the EPA STEL	ECEL and EPA STEL periodic monitoring at least once in every 5 years.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL	ECEL periodic required at least once every 5 years, and EPA STEL periodic monitoring required every 3 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and at or below the EPA STEL	ECEL periodic monitoring every 6 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and above the EPA STEL	ECEL periodic monitoring every 6 months and EPA STEL periodic monitoring every 3 months.

If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL	ECEL periodic monitoring every 3 months and EPA STEL periodic monitoring every 3 months.
If 2 consecutive monitoring events have taken place at least 7 days apart that indicate that potential exposure has decreased from above the ECEL to at or below the ECEL, but at or above the ECEL action level	Transition from ECEL periodic monitoring frequency from every 3 months to every 6 months.
If 2 consecutive monitoring events have taken place at least 7 days apart that indicate that potential exposure has decreased to below the ECEL action level and at or below the EPA STEL	Transition from ECEL periodic monitoring frequency from every 6 months to once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year periodic exposure monitoring must occur.
If the owner or operator engages in any conditions of use described in paragraph (a) of this section and is required to monitor either the ECEL or EPA STEL in a 3-month interval, but does not engage in any of those uses for the entirety of the 3-month interval	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene chloride must be maintained, and initial monitoring is required when the owner or operator resumes or starts any of the conditions of use described in paragraph (a) of this section.
Owner or operator engages in any conditions of use described in paragraph (a) of this section and is required to monitor the ECEL in a 6-month interval, but does not engage in any of those uses for the entirety of the 6-month interval	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of the condition(s) of use must be maintained until periodic monitoring resumes, and initial monitoring is required when the owner or operator resumes or starts any of the conditions of use described in paragraph (a) of this section.

(4) Additional monitoring. The owner or operator must conduct the exposure monitoring required by paragraph (d)(2) of this section within 30 days after any change that may reasonably be expected to introduce additional sources of exposure to methylene chloride, or otherwise result in increased exposure to methylene chloride compared to the most recent monitoring event. Examples of situations that may require additional monitoring include changes in production, process, control equipment, or work practices, or a leak, rupture, or other breakdown.

(5) Notification of monitoring results.

(i) The owner or operator must inform potentially exposed persons of monitoring results within 15 working days.

(ii) This notification must include the following:

(A) Exposure monitoring results;

(B) Identification and explanation of the ECEL, ECEL Action Level, and EPA STEL;

(C) Whether the airborne concentration of methylene chloride exceeds the ECEL action level, ECEL or the EPA STEL;

(D) If the ECEL or EPA STEL is exceeded, descriptions of actions taken by the owner or operator to reduce exposure in accordance with paragraph (e)(1)((i) of this section;

(E) Explanation of any required respiratory protection provided in accordance with as paragraphs (e)(1)(ii) and (f) of this section;

(F) Quantity of methylene chloride in use at the time of monitoring;

(G) Location of methylene chloride use at the time of monitoring;

(H) Manner of methylene chloride use at the time of monitoring; and

(I) Identified releases of methylene chloride.

(iii) Notice must be provided in plain language writing, in a language that the person understands, to each potentially exposed person or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non–English language version representing the language of the largest group of workers who do not read English.

(6) Observation of monitoring.

(i) The owner or operator must provide affected potentially exposed persons an opportunity to observe exposure monitoring conducted in accordance with this paragraph (d) that is representative of the potentially exposed person's exposure.

(ii) The owner or operator must ensure that potentially exposed persons are provided with personal protective equipment appropriate for the observation of monitoring.

(e) ECEL control procedures and plan—

(1) Methods of compliance.

(i) By May 10, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or by October 30, 2025 for other owners and operators, the owner or operator must institute one or a combination of elimination, substitution, engineering controls, work practices, or administrative controls to reduce exposure to or below the ECEL and EPA STEL except to the extent that the owner or operator can demonstrate that such controls are not feasible.

(ii) If the feasible controls, required by paragraph (e)(1)(i) of this section that can be instituted do not reduce exposures for potentially exposed persons to or below the ECEL or EPA STEL, then the owner or operator must use such controls to reduce exposure to the lowest levels achievable by these controls and must supplement those controls with the use of respiratory protection that complies with the requirements of paragraph (f) of this section to reduce exposures to or below the ECEL or EPA STEL.

(iii) Where an owner or operator cannot demonstrate exposure below the ECEL, including through the use of all feasible engineering controls, work practices, or administrative controls as described in paragraph (e)(1)(i) of this section, and, has not demonstrated that it has appropriately supplemented with respiratory protection that complies with the requirements of paragraphs (e)(1)(ii) and (f) of this section, this will constitute a failure to comply with the ECEL.

(iv) For the Department of Defense and Federal contractors acting for or on behalf of the Department of Defense, in the event that ongoing or planned construction is necessary to implement the feasible controls required by paragraph (e)(1)(i) of this section such that no one is exposed above the ECEL or EPA STEL, the deadlines in paragraph (e)(1)(i) of this section are extended to May 7, 2029. Ongoing or planned construction efforts to address exposures above the ECEL and EPA STEL must be documented in the exposure control plan required by paragraph (e)(2) of this section.

(2) Exposure control plan. By May 10, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or by October 30, 2025 for other owners and operators, the owner or operator must develop and implement an exposure control plan.

(i) Exposure control plan contents. The exposure control plan must include documentation of the following:

(A) Identification of exposure controls that were considered, including those that were used or not used to meet the requirements of paragraph (e)(1)(i) of this section, in the following sequence—elimination, substitution, engineering controls, and work practices and administrative controls;

(B) For each exposure control considered, a rationale for why the exposure control was selected or not selected based on feasibility, effectiveness, and other relevant considerations;

(C) A description of actions the owner or operator must take to implement the exposure controls selected, including proper installation, regular inspections, maintenance, training, or other actions;

(D) A description of regulated areas, how they are demarcated, and persons authorized to enter the regulated areas;

(E) A description of activities conducted by the owner or operator to review and update the exposure control plan to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls; and

(F) An explanation of the procedures for responding to any change that may reasonably be expected to introduce additional sources of exposure to methylene chloride, or otherwise result in increased exposure to methylene chloride, including procedures for implementing corrective actions to mitigate exposure to methylene chloride.

(ii) Exposure control plan requirements.

(A) The owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(B) The owner or operator must maintain the effectiveness of any controls, instituted under paragraph (e) of this section.

(C) The exposure control plan must be reviewed and updated as necessary, but at least every 5 years, to reflect any significant changes in the status of the owner or operator's approach to compliance with paragraphs (c) through (e) of this section.

(iii) Availability of exposure control plan.

(A) Owners or operators must make the exposure control plan and associated records, including exposure monitoring, respiratory protection program implementation, and dermal protection program implementation records, available to potentially exposed persons.

(B) Owners or operators must notify potentially exposed persons of the availability of the plan and associated records within 30 days of the date that the exposure control plan is completed and at least annually thereafter. The notification must be provided in accordance with the requirements of paragraph (d)(5)(iii) of this section.

(C) Upon request by the potentially exposed person, the owner or operator must provide the specified records at a reasonable time, place, and manner. If the owner or operator is unable to provide the requested records within 15 days, the owner or operator must, within those 15 days, inform the potentially exposed person requesting the record(s) of the reason for the delay and the earliest date when the record can be made available.

(3) Respirator requirements. The owner or operator must supply a respirator, selected in accordance with paragraph (f) of this section, to each potentially exposed person who enters a regulated area and must ensure each potentially exposed person uses that respirator whenever methylene chloride exposures may exceed the ECEL or EPA STEL.

(f) Respiratory protection—

(1) Respirator conditions. After February 8, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, after August 1, 2025 for other owners and operators, or within 3 months after receipt of the results of any exposure monitoring as described in paragraph (d) of this section, owners or operators must provide respiratory protection to all potentially exposed persons in the regulated area as outlined in paragraph (c)(3) of this section,

and according to the provisions outlined in 29 CFR 1910.134(a) through (l) (except 29 CFR 1910.134(d)(1)(iii)) and as specified in this paragraph (f) for potentially exposed persons exposed to methylene chloride in concentrations above the ECEL or the EPA STEL. For the purpose of this paragraph (f), the maximum use concentration (MUC) as used in 29 CFR 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL or EPA STEL.

(2) Respirator selection criteria. The type of respiratory protection that regulated entities must select and provide to potentially exposed persons in accordance with 29 CFR 1910.1052(g)(3)(i), is directly related to the monitoring results, as follows:

(i) If the measured exposure concentration is at or below the ECEL or EPA STEL: no respiratory protection is required.

(ii) If the measured exposure concentration is above 2 ppm and less than or equal to 50 ppm: the respirator protection required is any NIOSH Approved® supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).

(iii) If the measured exposure concentration is above 50 ppm and less than or equal to 100 ppm the respirator protection required is:

(A) Any NIOSH Approved® Supplied–Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or

(B) Any NIOSH Approved® Self–Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).

(iv) If the measured exposure concentration is unknown or at any value above 100 ppm and up to 2,000 ppm the respirator protection required is:

(A) Any NIOSH Approved® Supplied–Air Respirator (SAR) or airline respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood that has been tested to demonstrate performance at a level of a protection of APF 1,000 or greater. (APF 1,000); or

(B) Any NIOSH Approved® Supplied–Air Respirator (SAR) or airline respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply (APF 1,000); or

(C) Any NIOSH Approved® Self–Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 10,000).

(3) Minimal respiratory protection. Requirements outlined in paragraph (e)(2) of this section represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(g) Dermal protection.

(1) After February 8, 2027 for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or after August 1, 2025 for other owners and operators, owners or operators must require the donning of gloves that are chemically resistant to methylene chloride with activity-specific training where dermal contact with methylene chloride is possible, after application of the requirements in paragraph (e) of this section, in accordance with the NIOSH hierarchy of controls.

(2) Owners or operators must minimize and protect potentially exposed persons from dermal exposure in accordance with 29 CFR 1910.1052(h) and (i).

(h) Training. Owners or operators must provide training in accordance with 29 CFR 1910.1052(l)(1) through (6) to potentially exposed persons prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride. In addition, if respiratory protection or PPE must be worn within a regulated area, owners or operators must provide training in accordance with 29 CFR 1910.132(f) to potentially exposed persons within that regulated area.

Credits
[89 FR 39297, May 8, 2024]

SOURCE: 84 FR 11435, March 27, 2019, unless otherwise noted.

AUTHORITY: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

Current through October 9, 2024, 89 FR 82158. Some sections may be more current. See credits for details.

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IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEXAS CHEMISTRY COUNCIL and AMERICAN CHEMISTRY COUNCIL, et al., Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency, Respondents, OLIN CORPORATION, et al., Intervenors.	Case No. 24-1185

DECLARATION OF AMERICAN CHEMISTRY COUNCIL

I, Robert J. Simon, being duly sworn, state as follows:

1. I am over 18 years of age and suffer from no legal incapacity.

2. I have personal knowledge as to the matters stated herein.

3. I am Vice President, Chemical Products & Technology, for the American Chemistry Council ("**ACC**"). My office address is 700 2nd Street, N.E., Washington, District of Columbia, 20002.

The American Chemistry Council

4. ACC is a nationwide trade association of chemical manufacturers, transporters, and distributors. ACC represents more than 190 member companies across the United States whose missions include promotion of the economic and innovative growth of the chemical industry. ACC's member companies' businesses, operations, and products are directly governed and regulated by TSCA, and are therefore impacted by the outcome of EPA's existing chemical review process.

5. As leaders in the chemical industry, ACC's member companies regularly engage with EPA in its evaluation and regulation of existing chemicals under TSCA. For example, ACC's members have been required to respond to test orders issued by EPA under Section 4 of TSCA, 15 U.S.C. § 2603, to inform Risk Evaluations. These orders have required members to expend tens of thousands of dollars to comply with the order, including conducting the required testing. ACC serves as the consortium manager for several chemicals in the Risk Evaluation process including 1,2-dichloropropane; 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]; o-dichlorobenzene; p-dichlorobenzene; and phosphoric acid, triphenyl ester.

Overview of the TSCA Chemical Review Process

6. The Toxic Substances Control Act ("**TSCA**") was enacted in 1976 and amended in 2016 through the Frank R. Lautenberg Chemical Safety for the 21st

Century Act, to "regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances." Pub. Law 94-469 (Oct. 11, 1976) (the "**2016 Amendments**"). In the 2016 Amendments, Congress established a process for reviewing and evaluating existing chemicals, which requires EPA to: (1) prioritize certain existing chemicals as "high priority" for risk evaluation ("**Prioritization**"); and (2) identify and assess risks associated with certain uses of high priority chemicals ("**Risk Evaluation**"), and issue a determination as to whether there is an unreasonable risk for any of the identified uses ("**Risk Determination**"). Following issuance of a Risk Determination, TSCA directs EPA to implement regulations, to the extent necessary, to address any unreasonable risks identified for specific uses ("**Risk Management**").

7. ACC's members are impacted by every stage of this process, whether providing the necessary information to the agency or having to implement the resulting Risk Management requirements.

8. The first stage of the process—Prioritization—requires EPA to designate chemical substances as "high priority" or "low priority" based on "a consideration of the hazard and exposure potential" for the chemical. ACC's members provide comments during Prioritization as EPA addresses proposed

priority designations. Chemicals that are designated as "high priority" by EPA move forward to the second stage of the process, Risk Evaluation.

9. During the Risk Evaluation stage, EPA must determine whether a chemical substance presents "an unreasonable risk" which includes "an unreasonable risk to a potentially exposed or susceptible subpopulation" under "the conditions of use." During this stage, EPA requests, and may require through test orders, parties such as ACC member companies to submit information related to the manufacture, processing, use, or disposal of chemicals to inform EPA's Risk Evaluation. That information is often key to how EPA analyzes the hazards and exposure potential for the chemical. Before finalizing a Risk Evaluation, EPA will issue a draft for public comment. Responding to EPA's test orders or otherwise providing information and preparing substantive comments on a draft risk evaluation are very complex, expensive, and time consuming.

10. At the conclusion of the Risk Evaluation, EPA must issue a Risk Determination as to whether there is "unreasonable risk" or "no unreasonable risk" for any of the conditions of uses. For any conditions of use with unreasonable Risk Determination(s), EPA will move onto the Risk Management process to promulgate regulations to the extent necessary to manage any unreasonable risks associated with the uses of the chemical substance. This may include use prohibitions, worker protection requirements, concentration limits, record keeping, labeling, notification,

and other restrictions. Such conditions have an across the board impact on ACC's members, whether they are involved in the manufacture, transport, distribution, or use of the particular chemical.

The Risk Evaluation Rulemaking

11. On December 14, 2023, ACC filed comments on EPA's proposed amendments to the procedural framework rule for conducting risk evaluations under TSCA. *See* Comment Letter on Proposed Rule Regarding Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) ("**Comments**"). ACC's Comments pointed out numerous legal flaws in the proposed rule, including how it would significantly alter the processes and procedures utilized by EPA in conducting Risk Evaluations for existing chemicals under Section 6 of TSCA in contravention of Congressional directives issued in the statute.

12. EPA finalized the rule on May 3, 2024. *See* "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," 89 Fed. Reg. 37,028 (May 3, 2024) ("**Rule**"). Unfortunately, EPA did not alter the proposed rule to address ACC's Comments in any meaningful manner, even though its members, as chemical manufacturers, were listed as "potentially affected entities" by the Rule.

13. Accordingly, as noted by ACC in its Comments, the Rule changed the following statutory directives from Congress:

a. EPA decided that it will make risk determinations in the final Risk Evaluation on the chemical as a whole (the "**Whole Chemical Approach**"), rather than make separate risk determinations for each of the relevant uses,

b. EPA decided it would evaluate "all" conditions of use for an existing chemical during the risk evaluation process (the "All Conditions of Use Approach"), rather than selecting uses that have the greatest potential to pose risk per the requirements of the statute; and

c. EPA decided it would not assume the use of personal protective equipment ("**PPE**") by workers when evaluating chemical exposures (the "**No-PPE Assumption**"), even when required by law.

14. On May 23, 2024, ACC, along with the Texas Chemistry Council, filed a petition for review of the Rule. The case was transferred to and consolidated in the U.S. Court of Appeals for the D.C. Circuit on June 2, 2024.

The Impact of the Rule on ACC's Members

15. The chemical industry, including ACC's member companies, face a credible and immediate threat of injury from EPA's arbitrary and unlawful amendment to the regulatory process for conducting Risk Evaluations under Section 6 of TSCA. Significantly, EPA has already begun implementing these new processes and procedures into its recently finalized and currently ongoing Risk Evaluations of

several chemicals that are manufactured, processed, and used by ACC's member companies, including 1,1-dichloroethane, formaldehyde, and tris (2-chloroethyl) phosphate (TCEP), and intends to apply them to all future Risk Evaluations and Risk Determinations. Said another way, the Rule codified a significant change in practice by EPA. The Rule impacts ACC's members in numerous ways.

16. First, the Rule has resulted and will continue to result in a flawed and unreasonable regulatory process that has and will continue to cause ACC's members to experience imminent economic and operational harm during the Risk Evaluation process, and before a final Risk Determination is issued. For example, under Section 4 of TSCA, EPA issues test orders requiring chemical manufacturers to submit data and information to EPA during the Risk Evaluation process for certain conditions of use. Responses to this request involve significant costs and resources. Under the Whole Chemical Approach, ACC's members will be harmed by expending significant resources to provide information to EPA that is ultimately not used to inform the final Risk Determination. For example, when ACC members submit data to EPA demonstrating that a condition of use for a chemical does not pose an unreasonable risk, this data is not used to inform the Risk Determination if EPA determines that one or more other conditions of use for the chemical pose an unreasonable risk and issues an unreasonable Risk Determination for the whole

chemical. The Whole Chemical Approach improperly tilts the balance in favor of finding unreasonable risk.

17. ACC members are also required to expend resources to provide information about all conditions of use, instead of focusing on the uses that have the greatest potential to pose risk. For example, a Risk Evaluation conducted under the All Conditions of Use Approach will require information to inform the evaluations of uses that are already regulated by existing Occupational Safety and Health Administration ("**OSHA**") and federal environmental requirements.

18. Further, during the Risk Evaluation phase, ACC's members will be harmed by wasting significant resources to provide data related to industrial hygiene ("**IH**") and PPE controls under specific conditions of use. These harms are discussed in further detail in the declaration submitted by member company Occidental Chemical Corporation. Under the Rule, EPA has decided that it will not assume the use of PPE and similar controls required under worker protection laws when evaluating worker exposures to chemicals. Ignoring legally required use of PPE results in the risk of exposure being improperly evaluated.

19. Next, in the multi-year period after the unreasonable Risk Determination is issued, but before promulgation of the final Risk Management Rule, ACC's members will continue to face economic and operational harm as a result of the issuance of arbitrary and unreasonable Risk Determinations under the

Whole Chemical Approach for chemical substances that are currently manufactured, processed, and used by ACC's members. ACC's members that manufacture and sell chemicals that are subject to a flawed unreasonable Risk Determination will experience several economic and operational harms, including, but not limited to: (a) incurring significant, up to millions of dollars, costs to support technical, legal, and advocacy efforts to prevent unnecessary risk management rules; and (b) customer use deselection due to a misperception that the substance poses an unreasonable risk based upon the flawed Risk Evaluation.

Example of the Application of the Rule

20. The injury is not hypothetical. Specifically, ACC's members are experiencing actual, concrete, and substantial harm as a result of EPA's incorporation of the Whole Chemical Approach and No-PPE Assumption into the Risk Evaluation and Risk Determination for methylene chloride. Following EPA's original Risk Evaluation for methylene chloride in 2020, it issued a Risk Determination of "no unreasonable risk" for the manufacturing condition of use. However, in 2022, EPA issued a revised Risk Determination of unreasonable risk for the entire chemical under the Whole Chemical Approach and No-PPE Assumption without revising any of the exposure estimates or scientific assessments, which ultimately resulted in conditions of use that were previously determined to

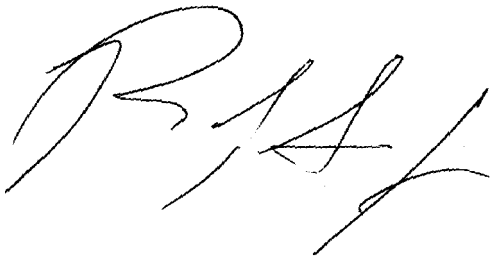
present no unreasonable risk (i.e., manufacturing) to be subject to regulation in the Risk Management phase.

21. As a result of the flawed Whole Chemical Approach, EPA's final Risk Management Rule for methylene chloride has resulted in ACC's members facing economic and operational harm by being subject to increased costs to implement operational compliance measures to comply with regulations for a condition of use that was previously determined—via scientific data and exposure information—to present no unreasonable risk. Compliance includes conducting baseline risk assessments in addition to the pre-existing IH sampling and compliance requirements under OSHA. These new TSCA compliance activities require the retention of consultants to perform IH sampling tasks that cannot be supported with existing staff and resources as well as additional sampling and laboratory analysis costs. Compliance obligations will be ongoing and in addition to compliance with the pre-existing OSHA workplace regulations, controls, and IH requirements.

22. A favorable decision from this Court would direct the TSCA Risk Evaluations and Risk Determinations to be lawfully based on the specific conditions of use determined relevant by the Administrator, on a conditions of use basis, and incorporate existing PPE requirements and controls. This would redress the injuries of ACC's members whose operations and businesses are currently being subject to

Risk Evaluations and Risk Determinations that are not driven by science or data, but rather incorporate arbitrary worst case assumptions by EPA.

I hereby declare under penalty of perjury that the foregoing is true and correct.



Robert J. Simon

Dated: October 10, 2024

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEXAS CHEMISTRY COUNCIL and AMERICAN CHEMISTRY COUNCIL, et al., Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency, Respondents, OLIN CORPORATION, et al., Intervenors.	Case No. 24-1185

DECLARATION OF TEXAS CHEMISTRY COUNCIL

I, Logan Harrell, being duly sworn, state as follows:

1. I am over 18 years of age and suffer from no legal incapacity.

2. I have personal knowledge as to the matters stated herein.

3. I am General Counsel and Director of Regulatory Affairs for the Texas Chemistry Council ("**TCC**"). My office address is 1402 Nueces Street, Austin, Texas 78701.

4. TCC represents 65 member companies who own and operate more than 200 manufacturing and research facilities across the State of Texas. Our members have over $250 billion in physical assets in the state, directly employ more than 80,000 Texans, and are responsible for 400,000 indirect industry jobs in the form of contractors, suppliers, and service providers that support the business of chemistry in Texas. Texas chemical manufacturing is the number one non-energy export in the state with over $50 billion in value annually.

5. Our members' businesses, operations, and products are directly regulated and affected by the Toxic Substances Control Act ("**TSCA**") and EPA's rules purporting to effectively implement the statutory language. Our members regularly engage with EPA in its evaluation and regulation of existing chemicals under TSCA. For example, TCC's members are often called upon to assist EPA in its risk evaluation process under TSCA Section 6 by responding to test orders under TSCA Section 4, which often require the expense of hundreds of thousands, if not millions, of dollars to prepare and submit detailed information regarding a chemical substance to EPA.

6. TCC's members are affected by every stage of the TSCA process when EPA evaluates an existing chemical, as described in the American Chemistry Council's declaration filed with this opening brief – from providing information to

EPA for Prioritization through implementing the requirements in a Risk Management Rule.

7. On May 3, 2024, EPA published the final rule titled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)." *See* 89 Fed. Reg. 37,028 (May 3, 2024) ("**Rule"**). TCC's members, as chemical manufacturers, were listed as "potentially affected entities" by the Rule.

8. TCC is concerned that the Rule drastically departed from Congress's statutory directives and intent imbued in TSCA in the following ways:

a. EPA decided it would evaluate all possible conditions of use for an existing chemical during a single risk evaluation process, (the "**All Conditions of Use Approach**"), rather than focusing on conditions of use that pose the greatest potential for risk of exposure;

b. EPA decided it will make risk determinations based on the chemical as a whole (the "**Whole Chemical Approach**"), rather than making risk determinations on a use-by-use basis (the "**Use-by-Use Approach**"); and

c. EPA decided it would disregard existing laws that require personal protective equipment ("**PPE**") to mitigate chemical exposure and assume workers do not use required PPE when

determining the risk of exposure ("**No-PPE Assumption**") in willful noncompliance with existing laws, despite TSCA directing EPA to evaluate all available information.

9. On May 23, 2024, TCC, along with the ACC, filed a petition for review of the Rule. On June 2, 2024, the case was transferred to and consolidated in the U.S. Court of Appeals for the D.C. Circuit.

10. The Rule codified significant changes in EPA's implementation of TSCA. TCC's member companies, and the chemical manufacturing industry as a whole, face a credible and immediate threat of injury from EPA's arbitrary and unlawful revision to the regulatory process for conducting Risk Evaluations under TSCA Section 6. Significantly, EPA has already begun implementing these new processes and procedures into its recently finalized and currently ongoing Risk Evaluations of several chemicals that are manufactured, processed, and used by TCC's member companies, including chrysotile asbestos, methylene chloride, formaldehyde, carbon tetrachloride, perchloroethylene, trichloroethylene, and n-methylpyrrolidone, and intends to apply them to all future Risk Evaluations and Risk Determinations. As already comprehensively discussed in ACC's declaration, the flawed Rule impacts TCC's members in substantially the same burdensome ways.

11. A favorable decision from this Court would direct the TSCA Risk Evaluations and Risk Determinations to be lawfully based on the specific conditions of use determined relevant by the Administrator, on a conditions of use basis, and to incorporate existing PPE requirements and controls. This would redress the injuries to TCC's members whose operations and businesses are currently being subjected to Risk Evaluations and Risk Determinations that are unlawful, not driven by science or data, and incorporate arbitrary worst-case assumptions by EPA.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Logan Harrell

Logan Harrell

Dated: October 10, 2024

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEXAS CHEMISTRY COUNCIL and AMERICAN CHEMISTRY COUNCIL, et al., Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency, Respondents, OLIN CORPORATION, et al., Intervenors.	)	Case No. 24-1185

DECLARATION OF OCCIDENTAL CHEMICAL CORPORATION

I, Anand Krishna, being duly sworn, state as follows:

1. I am over 18 years of age and suffer from no legal incapacity.

2. I have personal knowledge as to the matters stated herein.

3. I am Vice President of Health, Environment, Safety & Security for Occidental Chemical Corporation ("**OxyChem**"). My office address is 14555 Dallas Parkway, Suite 400, Dallas, Texas 75254. OxyChem is a member of the Texas Chemistry Council ("**TCC**") and the American Chemistry Council ("**ACC**").

4. OxyChem is a chemical company that owns and operates 21 chemical manufacturing plants in the United States. For several chemicals it manufactures and markets, OxyChem holds a leading market position in the United States. As a member of ACC and TCC, OxyChem's interests are represented in TCC's and ACC's petition for review of the order of Respondent Michael S. Regan, the Administrator of Respondent United States Environmental Protection Agency ("**EPA**"), promulgating the final rule titled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," 89 Fed. Reg. 37,028 (May 3, 2024) ("**Rule**"), dated May 3, 2024.

5. As leaders in the chemical industry, TCC's and ACC's members, including OxyChem, have direct interests in some of the chemicals that have been prioritized for review by EPA and/or are currently part of an ongoing risk evaluation by EPA.[1] The chemicals that TCC's and ACC's members, including OxyChem, manufacture, distribute, process and utilize are directly regulated under TSCA. Accordingly, chemical manufacturers, including OxyChem, participate in these ongoing and future risk evaluations to provide information to EPA necessary to conduct a thorough and thoughtful review. This requires considerable expenditures of time and company resources to respond to EPA's information requests and

[1] *See* U.S. EPA, *Ongoing and Completed Chemical Risk Evaluations under TSCA*, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under.

comment on EPA's analyses and proposed rules, which often includes the development and provision of highly technical and detailed process, operational and testing data. In turn, the result of the risk evaluations will impact how chemicals are ultimately manufactured, processed, and utilized. *See* ACC Declaration ¶ 16; *see also* TCC Declaration ¶ 10.

6. For example, OxyChem manufactures, as a product or byproduct, the following chemicals that EPA has prioritized for review and/or are currently assessing as part of an ongoing risk evaluation: 1,2-Dichloroethane; 1,1-Dichloroethane; 1,2-Trichloroethane; and trans-1,2-Dichloroethylene. EPA has applied the Rule to all risk evaluations currently in process, and therefore applies the Rule to the foregoing Chemicals. Accordingly, OxyChem's businesses and operations are subject to the process set forth in the Rule.

7. During this rulemaking process, ACC filed comments explaining the concerns with EPA's proposed risk evaluation rule given that it (a) utilizes a single risk determination (the "**Whole Chemical Approach**") that will require EPA to issue risk determinations based on the chemical as a whole, rather than on the previously used conditions of use basis ("**Use-by-Use Approach**"); (b) mandates that EPA evaluate "all" conditions of use for an existing chemical during the risk evaluation process, rather than selecting those uses that pose the greatest risk ("**All Conditions of Use Approach**"); and (c) requires EPA to disregard the use of personal protective

equipment ("**PPE**") requirements for workers when evaluating chemical exposures ("**No-PPE Assumption**").

8. EPA's Rule failed to address the concerns raised by ACC. Based upon EPA's implementation to date of these risk evaluations processes listed in paragraph 7, the Rule will result in risk evaluations and risk management rules that will not only impose increased economic and operational costs but also dilute staff time and plant resources assigned to other manufacturing operational and regulatory priorities. As also documented in the ACC Declaration, risk evaluations previously revised by EPA to incorporate the Whole Chemical Approach and No PPE Assumption has required, and the Rule will likely require in the future, ACC members such as OxyChem to be subject to inapplicable unreasonable risk determinations (and thus subject to subsequent risk management rules) which were based on worst case assumptions, do not meet TSCA's scientific standards, and do not account for existing regulatory PPE requirements.

9. For example, under the prior Use-by-Use Approach, conditions of use (e.g., manufacturing) determined as "no unreasonable risk" would have exited the TSCA review after the risk evaluation; now, an "unreasonable risk" determination under the Whole Chemical Approach inappropriately herds all uses, including those determined not to be unreasonable, through the risk management rule process and regulatory framework. This Whole Chemical Approach imposes financial harm on

chemical manufacturers, such as OxyChem, by requiring them to incur significant costs to provide EPA with requested data and information for conditions of use which are ultimately disregarded in a risk evaluation based on the Whole Chemical Approach. For example, in the risk evaluation for 1,1-Dichloroethane (1,1-DCA), OxyChem expended significant time and costs, including over $200,000 in costs through an industry workgroup formed for the 1,1-DCA TSCA review, to respond to test orders and provide EPA with industrial hygiene data and information related to the manufacturing condition of use. This data was ultimately ignored by EPA in the draft 1,1-DCA risk evaluation in favor of worst-case scenario data that did not provide an accurate picture of the exposures and hazards associated with OxyChem's condition of use of 1,1-DCA as a manufacturing byproduct. If finalized, EPA's decision to arbitrarily disregard relevant data would place an otherwise "no unreasonable risk" use in the risk management rule process subject to risk management rules and the associated economic losses and harm.

10. The Rule's All Conditions of Use Approach will further require ACC members to expend significant resources to provide EPA with requested data and information for conditions of use that do not have the greatest exposure potential.

11. EPA's decision to disregard the use of PPE under the Rule results in risk evaluations that overestimate hazards and exposures associated with the use of the chemical. Specifically, by failing to recognize procedures imposed under OSHA

regulations to adequately protect against any exposures for certain uses, including manufacturing uses, EPA's risk evaluations do not accurately represent potential exposure. Again, a flawed risk evaluation imposes harms through an inaccurate determination of risk and an over application of the TSCA risk management rules.

12. Compliance with the unnecessary and overly burdensome TSCA risk management rules that result from the Rule will impose economic harms, such as the retention of consultants to perform industrial hygiene sampling tasks that cannot be supported with existing staff and resources as well as additional sampling and laboratory analysis costs. Such compliance obligations will not result in a corresponding increased health benefit and will be ongoing in addition to compliance with the pre-existing OSHA workplace regulations, controls, and industrial hygiene requirements.

13. As demonstrated herein, the processes that have now been codified in the revised Rule have already imposed actual operational and financial requirements impacting ACC's and TCC's members such as OxyChem. This experience indicates that continued and ongoing application of the flawed risk evaluations practices finalized in the Rule will cause imminent harm, including significant operational requirements and financial costs due to a Rule that goes beyond the TSCA statutory requirements for risk evaluations. A favorable decision from this Court would direct the TSCA risk evaluations, and thus the subsequent risk management rules, to be

lawfully based upon the conditions of use – not just the substance itself – and also incorporate PPE as a part of that determination. Indeed, such a decision would be consistent with TSCA's direction to conduct risk evaluations by taking into account "the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance."

[SIGNATURE ON FOLLOWING PAGE]

I hereby declare under penalty of perjury that the foregoing is true and correct.

Anand Krishna

Dated: October 9, 2024