

Methylene Chloride

TSCA Regulation

Final Rule

Effective July 8, 2024





Exclusions

This rule does not apply to:

- Any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and
- Any food, food additive, drug, cosmetic, or device, as 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.

TSCA Section 6(a) Summary

(i) Prohibition of the manufacture, processing, and distribution of methylene chloride for all consumer use

(ii) Prohibition of most industrial and commercial use of methylene chloride

(iii) Workplace Chemical Protection Program for conditions of use includes:

- inhalation exposure concentration limits
- related workplace exposure monitoring
- exposure controls

(iv) Recordkeeping and downstream notification requirements for

- manufacturing,
- processing, and
- distribution in commerce



Applies to Methylene Chloride or Products containing $\geq 0.1\%$ Methylene Chloride

- Manufacturers (includes importers to US)
- Producers
- Distributors
- Users or
- Disposal

*products in which methylene chloride is present below 0.1% by weight are not subject to the restrictions outlined in this rulemaking.




Compliance Deadlines – Issued May 8, 2024

- Rule goes into effect July 8, 2024.
- Manufacturers must revise SDS by October 7, 2024
- Processors and distributors revise their SDS by December 4, 2024
- SEG development and Initial Monitoring – May 5, 2025
- Exemptions:
 - EPA is providing an additional year for agencies of the Federal government and their contractors, when acting for or on behalf of the Federal government, to comply with the below:
 - WCPP that includes:
 - Initial monitoring by November 9, 2026
 - Ensure that no person is exposed to methylene chloride exceeding the ECEL or EPA STEL by February 8, 2027 and
 - Implement an exposure control plan by May 10, 2027

Workplace Chemical Protection Program Required for Specific MC Usage:

- Domestic manufacturing
 - Import
 - Processing as a reactant
 - Processing for incorporation into a formulation, mixture, or reaction product
 - Processing in repackaging
 - Processing in recycling
 - Industrial and commercial use as a laboratory chemical
 - Industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft
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- Industrial or commercial use as a bonding agent for solvent welding
 - Industrial and commercial use as a processing aid
 - Industrial and commercial use for plastic and rubber products manufacturing
 - 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
 - Disposal

A photograph of an industrial facility, likely a chemical plant, at dusk. The scene features several tall distillation columns and a large white storage tank, all illuminated by warm lights. The sky is a deep blue, and the foreground shows some low-lying vegetation.

WCPPs Apply to use in production of other chemicals including:

- Refrigerant chemicals
- Production of battery separators for electric vehicles
- Use as a processing aid in a closed system
- Use as a laboratory chemical
- Use in plastic and rubber manufacturing, including polycarbonate production
- Use in solvent welding

Workplace Chemical Protection Program (WCPP) for Methylene Chloride Require:

Initial monitoring and SEG Development – by May 5, 2025

SEG Development and Monitoring for:

Users

Compliance with EPA exposure limits – ECEL 2ppm/STEL 16ppm and action level of 1ppm

Hierarchy of Controls must be applied to ensure no person exposed to at or above the ECEL or STEL after August 1, 2025

Hierarchy of Controls must be applied to ensure no person exposed to at or above the ECEL or STEL 90 days after initial monitoring (by May 5, 2025)

Full Exposure Control Plans implemented– by October 30, 2025

-Documenting selection of controls and maintenance of controls

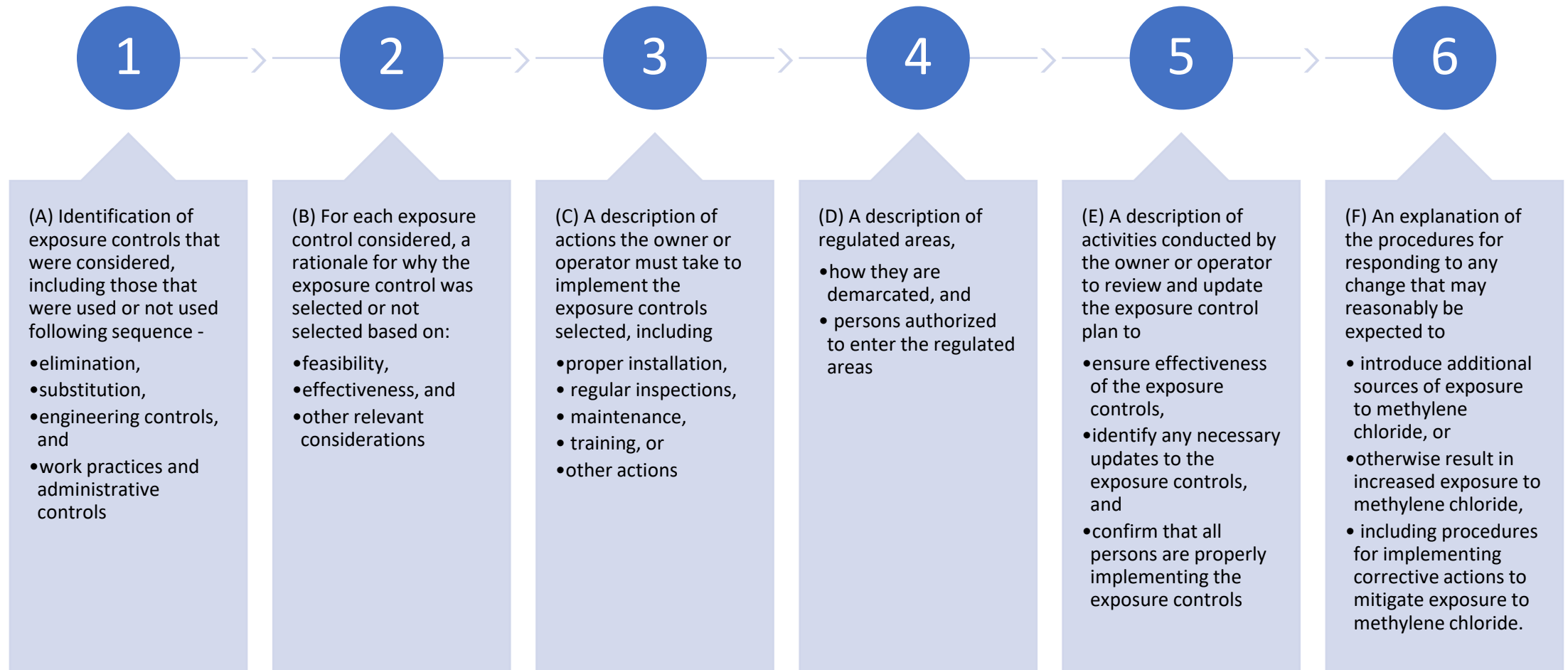
-Application of Hierarchy of Controls

-Specific worker training

-Recordkeeping and notification requirements

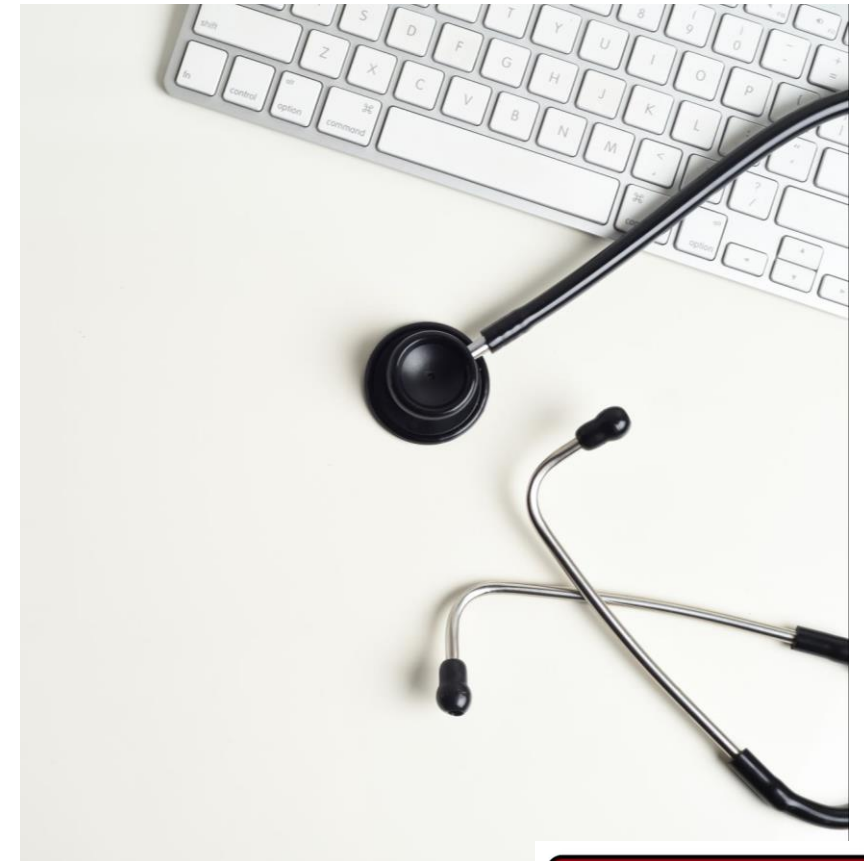
TSCA Exposure Control Plan Documentation

Due October 30, 2025



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 (Step 5 in previous slide).
- (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.





Exposure Control Plan Availability

- (A) Owners or operators must make the exposure control plan and associated records available to potentially exposed persons, including
- Exposure monitoring records
 - Respiratory protection program implementation
 - Dermal protection program implementation
- (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.
- (C) The owner or operator must provide the specified records at a reasonable time, place, and manner upon request by the potentially exposed person.

Exposure Monitoring Record Requirements for Owners/Operators

(1) monitoring records that include the information described in the OSHA Methylene Chloride Standard and the below:

(2) For each monitoring event of methylene chloride required under this subpart, must also document the following:

- (i) All measurements that may be necessary to determine the conditions that may affect the monitoring results;
- (ii) The identity of all other potentially exposed persons whose exposure was not measured and whose exposure is intended to be represented by the area or representative sampling monitoring;
- (iii) Use of established analytical methods;
- (iv) Compliance with the Good Laboratory Practice Standards or use of a laboratory accredited by the AIHA or another industry-recognized program; and
- (v) Information regarding air monitoring equipment including:
 - Type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.

(3) copies of exposure monitoring notifications provided to affected individuals

Personnel Breathing Zone Sampling Options

- For each potentially exposed person

OR

- Representative of each potentially exposed person's exposure per below:
 - (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.

Use of Objective Data and Real Time Monitoring

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 or

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.

Monitoring Requirements

Table 1 – Periodic Monitoring Requirements Based on Initial Exposure Monitoring Results

Air Concentration Condition	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 every 5 years.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL	ECEL periodic monitoring 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 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 of the conditions of use for which WCPP is finalized and is required to monitor either the ECEL or EPA STEL in a 3-month interval, but does not engage in any of those conditions of use for the entirety of the 3-month interval	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of manufacture, processing, use, or disposal of methylene chloride must be maintained, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which the WCPP is finalized.
If the owner or operator engages in any of the conditions of use for which WCPP is finalized and is required to monitor the ECEL in a 6-month interval, but does not engage in any of those conditions of use for the entirety of the 6-month interval	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of manufacture, processing, use, or disposal of methylene chloride must be maintained, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which the WCPP is finalized.

NOTE: Additional scenarios in which monitoring may be required are discussed in Unit IV.B.4.e.

Exposure Monitoring Results Notification

- When exposure to methylene chloride exceeds the ECEL action level within a regulated area, the owner or operator will be required to inform each potentially exposed person of the quantity, location, manner of use, release, and storage of methylene chloride and the specific operations in the workplace that could result in exposure to methylene chloride, particularly noting where exposures may be above the ECEL or EPA STEL.
- Within 15 working days after receipt of the results of any exposure monitoring, notify each potentially exposed person whose exposure is represented by that monitoring in writing, either individually to each potentially exposed person or by posting the information in an appropriate and accessible location, such as public spaces or common areas, for potentially exposed persons outside of the regulated area.
- The notice would be required to identify the ECEL, ECEL action level, and EPA STEL and what they mean in plain language, the exposure monitoring results, and any corresponding respiratory protection required.
- If the ECEL or EPA STEL is exceeded, the notice would also be required to include a description of the actions taken by the owner or operator to reduce inhalation exposures to or below the ECEL or EPA STEL which states the actions to be taken to reduce exposures.
- The notice must be posted in multiple languages if necessary (e.g., notice must be in a language that the potentially exposed person understands, including a non-English language version representing the language of the largest group of workers who cannot readily comprehend or read English).

Respiratory Protection Table 2

Table 2 – Respiratory Protection Conditions and Requirements

Concentration Condition	Minimum Required Respirator Protection
At or below the ECEL and EPA STEL	No respirator required.
Above ECEL (2 ppm) and less than or equal to 50 ppm (25 times the ECEL)	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).
Above 50 ppm and less than or equal to 100 ppm (50 times the ECEL)	Either (i) any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or (ii) any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).
Unknown concentration or at any value above 100 ppm and up to 2,000 ppm (1,000 times the ECEL)	One of (i) any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood (APF 1,000); or (ii) 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 (iii) 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).

Provision of Respiratory Protection

- Must provide respiratory protection sufficient to reduce inhalation exposures to below the ECEL or EPA STEL to all potentially exposed persons in the regulated area within three months after receipt of the results of any exposure monitoring.
 - For the private sector, this will be within 15 months after May 8, 2024.
 - For Federal agencies and Federal contractors acting for or on behalf of the Federal government, this will be within 21 months after May 8, 2024.

Regulated Areas

- Must demarcate any area where airborne concentrations of methylene chloride are reasonably expected to exceed the ECEL 2ppm or the EPA STEL 16 ppm.
- Must demarcate a regulated area within three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL or EPA STEL
- Must identify personnel who are authorized to enter regulated areas.
- Signs must clearly define regulated area and restrict access to authorized personnel
- The owner or operator is required to restrict access to the regulated area from any potentially exposed person that lacks proper training, PPE or is otherwise unauthorized to enter.

Signs must be in languages of personnel working at the location.

751.113 General Recordkeeping Requirements

(a) Each person who manufactures (including imports), processes, or distributes in commerce any methylene chloride after August 26, 2019, must retain in one location at the headquarters of the company, or at the facility for which the records were generated by July 8, 2024, **Documentation showing:**

- (1) The name, address, contact, and telephone number of companies to whom methylene chloride was shipped;
- (2) A copy of the notification provided under § 751.111; and
- (3) The amount of methylene chloride shipped.

(b) Exposure control records

Owners or operators must retain records of:

- (1) The exposure control plan
- (2) Implementation of the exposure control plan described, including: (i) Any regular inspections, evaluations, and updating of the exposure controls to maintain effectiveness; and (ii) Confirmation that all persons are properly implementing the exposure controls.
- (3) Personal protective equipment (PPE) and respiratory protection used by potentially exposed persons and program implementation, including fit-testing
- (4) Information and training provided on respiratory protection and
- (5) Occurrence and duration of any start-up, shutdown, or malfunction of exposure controls or of facility equipment that causes air concentrations to be above the ECEL or EPA STEL and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to methylene chloride.

(c) Objective data.

Objective data generated during the previous 5 years, when used to forgo the initial exposure monitoring, must include:

- (1) The use of methylene chloride being evaluated;
- (2) The source of objective data,
- (3) The measurement methods, measurement results, and measurement analysis of the use of methylene chloride; and
- (4) Any other relevant data to the operations, processes, or person's exposure.

WCPP Record Retention Requirements:



EXPOSURE CONTROL PLANS



REGULATED AREAS AND
AUTHORIZED PERSONNEL



FACILITY EXPOSURE
MONITORING RECORDS



NOTIFICATIONS OF
EXPOSURE MONITORING
RESULTS



PPE AND RESPIRATORY
PROTECTION USED AND
PROGRAM
IMPLEMENTATION



INFORMATION AND
TRAINING REQUIRED UNDER
OSHA METHYLENE
CHLORIDE STD APPENDIX A,

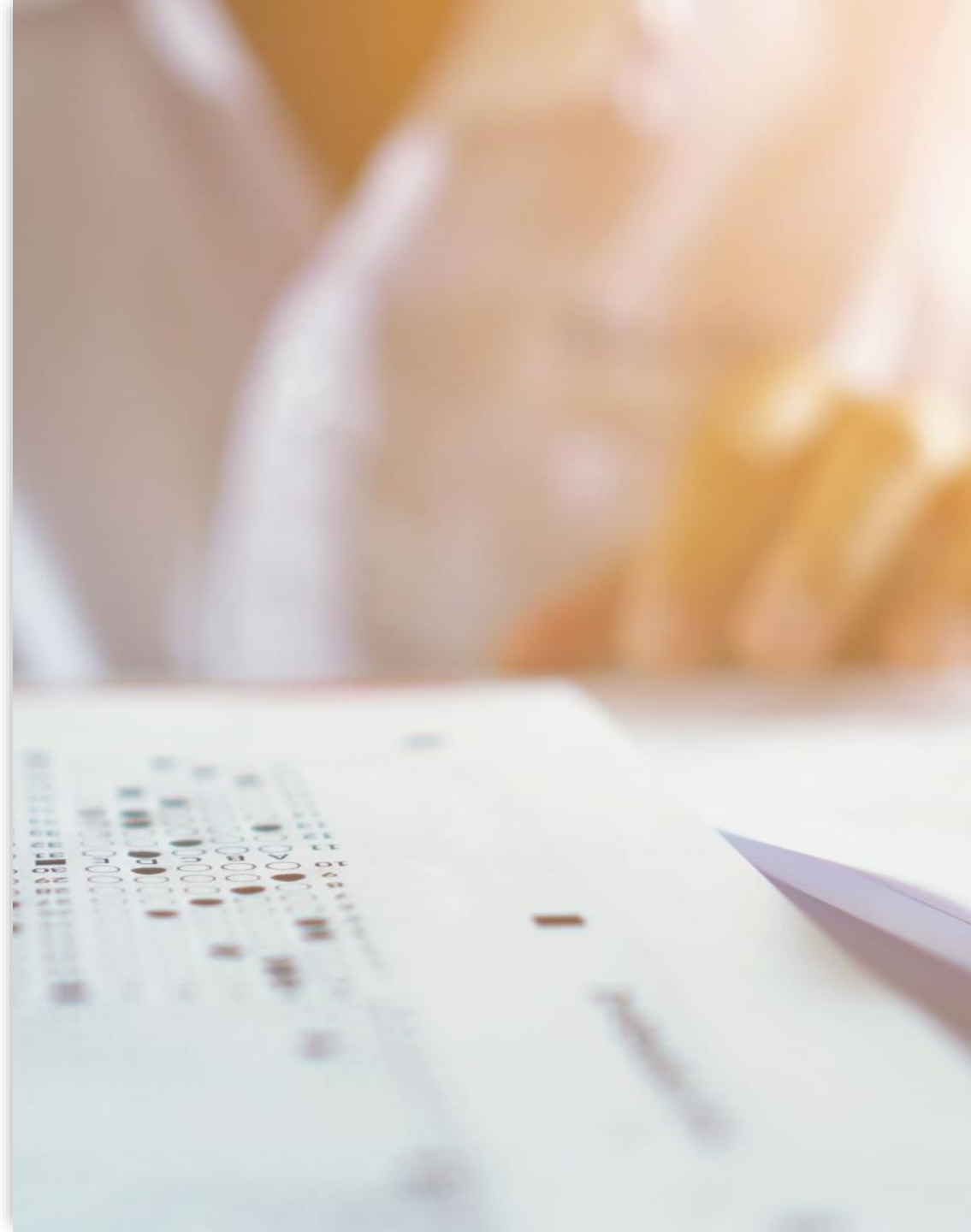
Business Records Retention

- Must maintain ordinary business records, such as
 - invoices
 - bills-of-lading

that demonstrate compliance with restrictions and other provisions of this final regulation

- Must maintain such records for a period of five years from the date the record is generated.

*This requirement begins July 8, 2024.



Access to Records, Exemptions and Retention

(e) Availability of exposure control plans.

- Owners or operators must document the notice to and ability of any potentially exposed persons to access the exposure control plan and other associated records

(h) Minimum record retention period.

- The records required under this section must be retained for at least 5 years from the date that such records were generated.
- Exposure control plan and associated records available to potentially exposed persons, at a reasonable time, place, and manner, within 15 working days of receiving a request.

OSHA Referenced Standards

- Any provisions applying to “employee” in 29 CFRs below apply equally to potentially exposed persons
 - 1910.132
 - 1910.134 and
 - 1910.1052 and
- Any provisions applying to “employer” in 29 CFRs below apply equally to any owner or operator for regulated areas
 - 1910.132
 - 1910.134 and
 - 1910.1052

Questions??

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Emergency Use of Methylene Chloride

- An emergency is a serious and sudden situation requiring immediate action, within 15 days or less, necessary to protect:
 - Safety of the National Aeronautics and Space Administration's or their contractors' personnel;
 - The National Aeronautics and Space Administration's missions;
 - Human health, safety, or property, including that of adjacent communities; or
 - The environment.
- Each emergency is a separate situation; if use of methylene chloride exceeds 15 days, then justification must be documented.

Emergency Eligibility - Exemption

The National Aeronautics and Space Administration and its contractors must:

- (i) Select methylene chloride because there are no technically and economically feasible safer alternatives available during the emergency.
- (ii) Perform the emergency use of methylene chloride at locations controlled by the National Aeronautics and Space Administration or its contractors.
- (iii) Comply with the following conditions:
 - (A) Notification. Within 15 working days of the emergency use by the National Aeronautics and Space Administration or its contractors, the National Aeronautics and Space Administration and its contractors must provide notice to the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention that includes the following: (1) Identification of the condition of use detailed in paragraph (b)(1) of this section to which the emergency use applies; (2) An explanation for why the emergency use met the definition of emergency in paragraph (b)(2)(i) of this section; and (3) An explanation of why methylene chloride was selected, including why there were no technically and economically feasible safer alternatives available in the particular emergency.
 - (B) Exposure. The owner or operator must comply with and document such compliance efforts under the Workplace Chemical Protection Program provisions in § 751.109, to the extent technically feasible in light of the particular emergency.
 - (C) Recordkeeping. The owner or operator of the location where the use takes place must comply with the recordkeeping requirements in § 751.113.



Exemptions

10-year time-limited exemptions under TSCA section 6(g) for:

- (v) civilian aviation from the prohibition addressing the use of methylene chloride for paint and coating removal to avoid significant disruptions to critical infrastructure, with conditions for this exemption to include compliance with the WCPP
- (vi) emergency use of methylene chloride in furtherance of the National Aeronautics and Space Administration's mission for specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available, with conditions for this exemption to include compliance with the WCPP.

Manufacturing Prohibition Timeframes

- After February 3, 2025, for distributing to retailers
- After May 5, 2025, for retailers distributing more broadly
- After May 5, 2025, for manufacturing and importing
- After August 1, 2025, for processors
- After January 28, 2026, for all other distributors and
- After April 28, 2026 for industrial and commercial users

