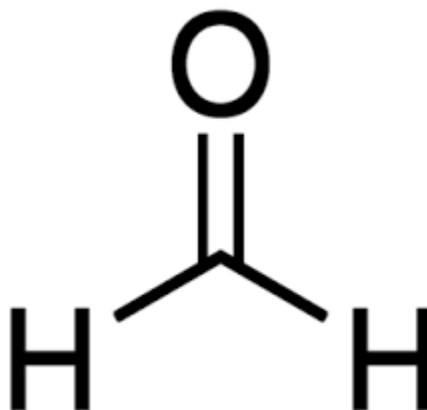




United States
Environmental Protection Agency

Conditions of Use of the Draft Risk Evaluation for Formaldehyde

CASRN 50-00-0



March 2024

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1 INTRODUCTION

This document provides an overview of the conditions of use (COUs) considered for the draft formaldehyde risk evaluation, pursuant to the Toxic Substances Control Act (TSCA) section 3(4) definition of “conditions of use” and TSCA section 3(2) definition of “chemical substance.” EPA does not intend to directly assess risk from any formaldehyde exposures occurring from non-TSCA uses (*e.g.*, exposures from biogenic production of formaldehyde or uses excluded from the TSCA section 3(2) definition of chemical substance, such as pesticides used for embalming and taxidermy as well as any food, food additive, drug, cosmetic, or device) in the draft formaldehyde risk evaluation. However, EPA did consider potential background exposures from non-TSCA uses, as appropriate, to help inform the Agency’s risk determination for formaldehyde under the TSCA conditions of use. This document also presents an explanation of the scope of certain conditions of use of formaldehyde and explains EPA’s rationale for any changes to the scope of the risk evaluation after publication of the *Final Scope for the Risk Evaluation for Formaldehyde CASRN 50-00-0* {U.S. EPA, 2020, 10617344} (2020 Final Scope).

2 RISK EVALUATION SCOPE

The TSCA draft risk evaluation of formaldehyde comprises several human health and environmental assessment modules and two risk assessment documents—the environmental risk assessment and the human health risk assessment. A basic diagram showing the layout of these modular assessments and their relationships is provided in Figure 2-1. In some cases, individual assessments were completed jointly under TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These modules are shown in dark gray.

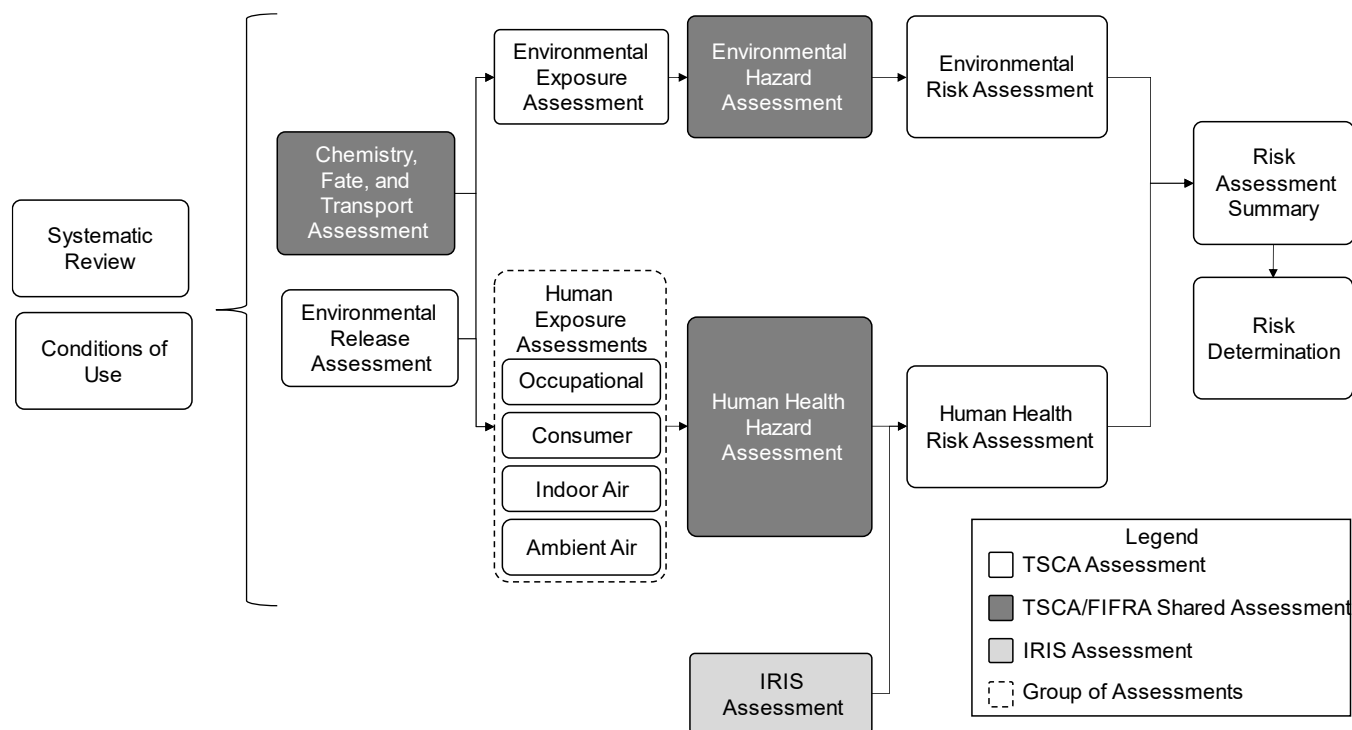


Figure 2-1. Risk Evaluation Document Summary Map

2.1 Conditions of Use Included in the Draft Risk Evaluation

The *Final Scope for the Risk Evaluation for Formaldehyde CASRN 50-00-0* {U.S. EPA, 2020, 10617344} (2020 Final Scope) identified and described the categories and subcategories of COUs that

EPA planned to consider in the formaldehyde risk evaluation. TSCA section 3(4) defines “conditions of use” (COUs) as “the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” Table 2-1 presents all COUs for formaldehyde.

In this draft risk evaluation, EPA has edited the formaldehyde COUs listed in the 2020 Final Scope. These edits reflect EPA’s improved understanding of formaldehyde’s COUs based on further outreach, public comments received, and updated industry code names under the Chemical Data Reporting (CDR) for 2020. These edits included (1) updated additions based on new reporting in CDR for 2020, (2) name changes based on new industry codes used in CDR for 2020, and (3) changes based on EPA’s further understanding of non-TSCA uses for formaldehyde that were initially included as TSCA COUs for formaldehyde in the 2020 Final Scope. EPA further examined some COU subcategories included in the 2020 Final Scope and determined that the subcategories were not formaldehyde COUs, either because EPA determined that the uses are excluded from the TSCA section 3(2) definition of “chemical substance” or that the uses are not actually circumstances under which formaldehyde is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. These subcategories are further discussed in Section 2.3 and have been removed from this draft risk evaluation.

EPA may further refine the description of the formaldehyde COUs included in the risk evaluation when the Final Risk Evaluation for Formaldehyde is published based upon peer review and public comment.

Table 2-1 presents the revised COUs that were included and evaluated in this Draft Risk Evaluation for Formaldehyde.

Table 2-1. Conditions of Use Included in the Draft Risk Evaluation for Formaldehyde

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Manufacturing	Domestic manufacturing	Domestic Manufacturing	U.S. EPA (2019a)
Manufacturing	Importing	Importing	U.S. EPA (2019a)
Processing	Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; basic organic chemical manufacturing	U.S. EPA (2019a)
Processing	Reactant	Intermediate in: Pesticide, fertilizer, and other agricultural chemical manufacturing; Petrochemical manufacturing; Soap, cleaning compound, and toilet preparation manufacturing; Basic organic chemical manufacturing; Plastic materials and resin manufacturing; Adhesive manufacturing; Chemical product and preparation manufacturing; Paper manufacturing; Paint and coating manufacturing; Plastic products manufacturing; Synthetic rubber manufacturing; Wood product manufacturing; Construction; Agriculture, forestry, fishing, and hunting	U.S. EPA (2019a)

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Processing	Reactant	Functional fluid in: Oil and gas drilling, extraction, and support activities	U.S. EPA (2019a)
Processing	Reactant	Processing aids, specific to petroleum production in all other basic chemical manufacturing	U.S. EPA (2019a)
Processing	Reactant	Bleaching agent in wood product manufacturing	U.S. EPA (2019a)
Processing	Reactant	Agricultural chemicals in agriculture, forestry, fishing, and hunting	U.S. EPA (2019a)
Processing	Incorporation into an article	Finishing agents in textiles, apparel, and leather manufacturing	U.S. EPA (2019a) ; USTMA (EPA-HQ-OPPT-2018-0438-0054)
Processing	Incorporation into an article	Paint additives and coating additives not described by other categories in transportation equipment manufacturing (including aerospace)	U.S. EPA (2019a) ; AIA (EPA-HQ-OPPT-2018-0438-0006)
Processing	Incorporation into an article	Additive in rubber product manufacturing	USTMA (EPA-HQ-OPPT-2018-0438-0026); USTMA (EPA-HQ-OPPT-2018-0438-0054)
Processing	Incorporation into an article	Adhesives and sealant chemicals in wood product manufacturing; plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction (including roofing materials); paper manufacturing	U.S. EPA (2019a) ; AIA (EPA-HQ-OPPT-2018-0438-0006); ARMA (EPA-HQ-OPPT2018-0438-0005); ARMA (EPA-HQ-OPPT-2018-0438-0051); USTMA (EPA-HQOPPT-2018-0438-0054)
Processing	Incorporation into a formulation, mixture, or reaction product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; and petroleum and coal products manufacturing	U.S. EPA (2019a) ; AIA (EPA-HQ-OPPT-2018-0438-0006); Everlube (EPA-HQ-OPPT2018-0438-0024)
Processing	Incorporation into a formulation, mixture, or reaction product	Asphalt, paving, roofing, and coating materials manufacturing	U.S. EPA (2019a) ; ARMA (EPA-HQ-OPPT-2018-0438-0005)
Processing	Incorporation into a formulation, mixture, or reaction product	Solvents (which become part of a product formulation or mixture) in paint and coating manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing	U.S. EPA (2019a) ; AIA (EPAHQ-OPPT-2018-0438-0006); EDF (EPA-HQ-OPPT-2018-0438-0017)

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Processing	Incorporation into a formulation, mixture, or reaction product	Paint additives and coating additives not described by other categories in: Paint and coating manufacturing; Plastic material and resin manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Intermediate in: all other basic chemical manufacturing; chemical product and preparation manufacturing; plastic material and resin manufacturing; oil and gas drilling, extraction, and support activities; wholesale and retail trade	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Solid separation agents in miscellaneous manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Agricultural chemicals (nonpesticidal) in: Agriculture, forestry, fishing, and hunting; pesticide, fertilizer, and agricultural chemical manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Surface active agents in plastic material and resin manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Ion exchange agents in adhesive manufacturing and paint and coating manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Lubricant and lubricant additive in adhesive manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Plating agents and surface treating agents in all other chemical product and preparation manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Soap, cleaning compound, and toilet preparation manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Laboratory chemicals	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Adhesive and sealant chemical in adhesive manufacturing	U.S. EPA (2019a)
Processing	Incorporation into a formulation, mixture, or reaction product	Bleaching agents in textile, apparel, and leather manufacturing	U.S. EPA (2019a)
Processing	Repackaging	Sales to distributors for laboratory chemicals	U.S. EPA (2019a)
Processing	Recycling	Recycling	U.S. EPA (2019a)
Distribution in Commerce	Distribution in commerce	Distribution in commerce	

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Industrial Use	Non-incorporative activities	Process aid in: Oil and gas drilling, extraction, and support activities; process aid specific to petroleum production, hydraulic fracturing	U.S. EPA (2019a) ; EDF (EPAHQ-OPPT-2018-0438-0017)
Industrial Use	Non-incorporative activities	Used in: construction	U.S. EPA (2019a)
Industrial Use	Non-incorporative activities	Oxidizing/reducing agent; processing aids, not otherwise listed	IPC (EPA-HQ-OPPT-2018-0438-0025); IPC (EPA-HQ-OPPT0438-0050); SAI (EPA-HQ-OPPT-0438-0053)
Industrial Use	Chemical substances in industrial products	Paints and coatings; adhesives and sealants; lubricants	AIA (EPA-HQ-OPPT-2018-0438-0006)
Commercial Uses	Chemical substances in furnishing treatment/care products	Floor coverings; Foam seating and bedding products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; Cleaning and furniture care products; Leather conditioner; Leather tanning, dye, finishing impregnation and care products; Textile (fabric) dyes; Textile finishing and impregnating/ surface treatment products.	U.S. EPA (2020a) ; U.S. EPA (2019a) ;
Commercial Uses	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019a)
Commercial Uses	Chemical substances in treatment/care products	Laundry and dishwashing products	U.S. EPA (2019a)
Commercial Uses	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	U.S. EPA (2019a)
Commercial Uses	Chemical substances in furnishing treatment/care products	Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	U.S. EPA (2019a) ; U.S. EPA (2020a)
Commercial Uses	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles	U.S. EPA (2019a)
Commercial Uses	Chemical substances in metal products	Construction and building materials covering large surface areas, including metal articles	U.S. EPA (2019a) ;

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Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Commercial uses	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	U.S. EPA (2019a) ; USTMA (EPA-HQ-OPPT-2018-0438-0026); Everlube (EPA-HQ-OPPT-2018-0438-0024)
Commercial uses	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019a)
Commercial Uses	Chemical substances in outdoor use products	Explosive materials	U.S. EPA (2019a)
Commercial Uses	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	U.S. EPA (2019a) ; ACA (EPA-HQ-OPPT-2018-0438-0023); ACC (EPA-HQ-OPPT-2018-0438-0018)
Commercial uses	Chemical substances in packaging, paper, plastic, hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019a)
Commercial Uses	Chemical substances in packaging, paper, plastic, hobby products	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019a) ;
Commercial Uses	Chemical substances in products not described by other codes	Laboratory Chemicals	U.S. EPA (2019a)
Consumer Uses	Chemical substances in furnishing treatment/care products	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles	U.S. EPA (2019a) ; U.S. EPA (2020a)
Consumer Uses	Chemical substances in furnishing treatment/care products	Fabric, textile, and leather products not covered elsewhere (clothing)	U.S. EPA (2019a) ; U.S. EPA (2020a)
Consumer Uses	Chemical substances in treatment products	Water treatment products	U.S. EPA (2019a)
Consumer Uses	Chemical substances in treatment/care products	Laundry and dishwashing products	U.S. EPA (2019a)
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Adhesives and Sealants; Paint and coatings	U.S. EPA (2019a)

Life Cycle Stage ^a	Category ^b	Subcategory ^c	Reference(s)
Consumer Uses	Chemical substances in construction, paint, electrical, and metal products	Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles	U.S. EPA (2019a) ; U.S. EPA (2020a)
Consumer Uses	Chemical substances in electrical products	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles	U.S. EPA (2019a)
Consumer Uses	Chemical substances in automotive and fuel products	Automotive care products; Lubricants and greases; Fuels and related products	U.S. EPA (2019a) ; USTMA (EPA-HQ-OPPT-2018-0438-0026); Everlube (EPA-HQ-OPPT-2018-0438-0024)
Consumer Uses	Chemical substances in agriculture use products	Lawn and garden products	U.S. EPA (2019a)
Consumer Uses	Chemical substances in packaging, paper, plastic, hobby products	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	U.S. EPA (2019a) ; ACA (EPA-HQ-OPPT-2018-0438-0023); ACC (EPA-HQ-OPPT-2018-0438-0018)
Consumer Uses	Chemical substances in hobby products	Arts, crafts, and hobby materials	U.S. EPA (2019a)
Consumer Uses	Chemical substances in packaging, paper, and plastic	Ink, toner, and colorant products; Photographic supplies	U.S. EPA (2019a)
Disposal	Disposal	Disposal	U.S. EPA (2019a)

^a Life Cycle Stage Use Definitions (40 CFR § 711.3)

- “Industrial use” means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed.
- “Commercial use” means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services.
- “Consumer use” means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use.
- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over “any manner or method of commercial use” under TSCA Section 6(a)(5) to reach both.

^b These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent conditions of use of Formaldehyde in industrial and/or commercial settings and for consumer uses.

^c These subcategories reflect more specific conditions of use of formaldehyde.

2.1.1 Additions and Name Changes to Conditions of Use Based on Updated 2020 CDR Reported Data

After the 2020 Final Scope, EPA received updated submissions under the 2020 CDR reported data. In addition to new submissions received under the 2020 CDR, the reporting name codes changed for the

2020 CDR reporting cycle. Therefore, EPA is amending the description of certain formaldehyde COUs based on those new submissions and new reporting name codes. Table 2-2 summarizes the changes to the COUs based on the new reporting codes in the 2020 CDR. These changes are included in Table 2-1.

Table 2-2. Additions and Name Changes to Categories and Subcategories of Conditions of Use Based on Updated Reporting in the 2020 CDR

Life Cycle Stage and Category	Original Subcategory in the 2020 Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing – Reactant	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; All other basic organic chemical manufacturing	Added – ‘Paint and coating manufacturing’	Adhesives and sealant chemicals in: Plastic and resin manufacturing; Wood product manufacturing; Paint and coating manufacturing; Basic organic chemical manufacturing
Processing – Reactant	Intermediate in: Pesticide, fertilizer, and other agricultural chemical manufacturing; Petrochemical manufacturing; Soap, cleaning compound, and toilet preparation manufacturing; All other basic organic chemical manufacturing; Plastic materials and resin manufacturing; Adhesive manufacturing; All other chemical product and preparation manufacturing; Paper manufacturing; Plastic products manufacturing; Wood product manufacturing; Construction; Agriculture, forestry, fishing, and hunting	Added – ‘Paint and coating manufacturing’ Added – ‘Synthetic rubber manufacturing’	Intermediate in: Pesticide, fertilizer, and other agricultural chemical manufacturing; Petrochemical manufacturing; Soap, cleaning compound, and toilet preparation manufacturing; basic organic chemical manufacturing; Plastic materials and resin manufacturing; Adhesive manufacturing; chemical product and preparation manufacturing; Paper manufacturing; Paint and coating manufacturing; Plastic products manufacturing; Synthetic rubber manufacturing; Wood product manufacturing; Construction; Agriculture, forestry, fishing, and hunting
Processing – Incorporation into a Formulation, Mixture, or Reaction Product	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; and all other basic organic chemical manufacturing	Added – ‘Petroleum and coal products manufacturing’	Petrochemical manufacturing, petroleum, lubricating oil and grease manufacturing; fuel and fuel additives; lubricant and lubricant additives; basic organic chemical manufacturing; and petroleum and coal products manufacturing
Processing – Incorporation into a Formulation, Mixture, or Reaction Product	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; and all other basic inorganic chemical manufacturing	Added – ‘Chemical product and preparation manufacturing’	Processing aids, specific to petroleum production in: oil and gas drilling, extraction, and support activities; chemical product and preparation manufacturing; and basic inorganic chemical manufacturing
Processing – Incorporation into a Formulation, Mixture, or Reaction Product	Functional fluids (closed system) in Soap, cleaning compound, and toilet preparation manufacturing	Name change based on new industry code	Soap, cleaning compound, and toilet preparation manufacturing

Life Cycle Stage and Category	Original Subcategory in the 2020 Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Commercial Use – Chemical Substances in Furnishing Treatment/Care Products	Floor coverings; Foam seating and bedding products; Furniture and furnishings not covered elsewhere; Cleaning and furniture care products; Fabric, textile, and leather products not covered elsewhere	Name change based on new industry code	Floor coverings; Foam seating and bedding products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; Cleaning and furniture care products; Leather conditioner; Leather tanning, dye, finishing impregnation and care products; Textile (fabric) dyes; Textile finishing and impregnating/ surface treatment products.
Commercial Use – Chemical Substances in Furnishing Treatment/Care Products	Building/construction materials – wood and engineered wood products; Building/ construction materials not covered elsewhere	Name change based on new industry code	Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Commercial Use – Chemical Substances in Electrical Products	Electrical and electronic products	Name change based on new industry code	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles
Commercial Use – Chemical Substances in Metal Products	Metal products not covered elsewhere	Name change based on new industry code	Construction and building materials covering large surface areas, including metal articles
Consumer Use – Chemical Substances in Furnishing Treatment/Care Products	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture and furnishings not covered elsewhere	Name change based on new industry code	Floor coverings; Foam seating and bedding products; Cleaning and furniture care products; Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles
Consumer Use – Chemical Substances in Furnishing Treatment/Care Products	Building/construction materials – wood and engineered wood products; Building/ construction materials not covered elsewhere	Name change based on new industry code	Construction and building materials covering large surface areas, including wood articles; Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
Consumer Use – Chemical Substances in Electrical Products	Electrical and electronic products	Name change based on new industry code	Machinery, mechanical appliances, electrical/electronic articles; Other machinery, mechanical appliances, electronic/electronic articles

2.2 Activities Determined Not to Be Conditions of Use

Section 2.2.2 of the 2020 Final Scope explained that EPA determined that several uses of formaldehyde were outside the scope of TSCA, such as pesticidal uses regulated under FIFRA. Among other things, TSCA section 3(2) excludes from the “chemical substance” definition “any pesticide (as defined in [FIFRA]) when manufactured, processed, or distributed in commerce for use as a pesticide,” “tobacco or any tobacco product,” and “any food, food additive, drug, cosmetic, or device (as such terms are defined in...the Federal Food, Drug, and Cosmetic Act (FFDCA) . . .) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device” (TSCA section 3(2)(B)(ii), (iii), (vi)).

When developing this draft risk evaluation, EPA concluded that some subcategories of the conditions of use listed in the final scope are either excluded from the TSCA section 3(2) definition of “chemical substance” or not actually circumstances under which formaldehyde is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. Therefore, EPA has removed these subcategories from the risk evaluation. Table 2-3 summarizes the changes to the COU subcategory descriptions.

Table 2-3. Subcategories Removed from the Risk Evaluation

Life Cycle Stage and Category	Original Subcategory in the 2020 Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Processing; Incorporation into a Formulation, Mixture, or Reaction Product	Other: Preservative in all other chemical product and preparation manufacturing	Removed	N/A
Industrial Use; Non-incorporative Activities	Used in: construction and agriculture, forestry, fishing, and hunting	Removed “and agriculture, forestry, fishing, and hunting”	Used in: construction
Commercial Use; Chemical Substances in Treatment/Care Products	Laundry and dishwashing products; Personal care products (covered by TSCA)	Removed “Personal care products (covered by TSCA)”	Laundry and dishwashing products
Commercial Use; Chemical Substances in Packaging, Paper, Plastic, Hobby Products	Food packaging; Paper products; Plastic and rubber products; Toys, playground, and sporting equipment	Removed “Food packaging”	Paper products; Plastic and rubber products; Toys, playground, and sporting equipment
Commercial Use; Chemical Substances in Products Not Described by Other Codes	Laboratory Chemicals (<i>e.g.</i> , specimen preservation, medical samples, mortuary science)	Removed “(<i>e.g.</i> , specimen preservation, medical samples, mortuary science)”	Laboratory Chemicals

Life Cycle Stage and Category	Original Subcategory in the 2020 Final Scope Document	Occurred Change	Revised Subcategory in the 2024 Draft Risk Evaluation
Consumer Use; Chemical Substances in Treatment/Care Products	Laundry and dishwashing products; Personal care products (covered by TSCA)	Removed “Personal care products (covered by TSCA)”	Laundry and dishwashing products

These activities were removed from the scope of the risk evaluation for the following reasons:

- *Processing, incorporation into a formulation, mixture, or reaction product, “Other: Preservative in all other chemical product and preparation manufacturing”* was removed after EPA determined that this is a pesticidal use under FIFRA. These preservative products meet the definition of “pesticide” under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA section 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for these uses. (Related: see *Commercial Use, Laboratory Chemicals, “specimen preservation, medical samples, mortuary science”* below.)
- *Industrial Use, Non-incorporative activities, “agriculture, forestry, fishing, and hunting”* was removed after EPA determined that this is not a circumstance under which formaldehyde is intended, known, or reasonably foreseen to be used. Based on additional information provided by the submitter of the 2016 CDR submission identifying this subcategory, EPA believes that the correct interpretation of the submission is of an incorporative activity involving the use of formaldehyde in the manufacture of animal feeds for agriculture and aquaculture/hatchery usage ([Bakelite EPA-HQ-OPPT-2018-0438-0134](#)). Depending on the particular facts, use of formaldehyde in animal feed meets the definition of a food, food additive, or drug under the FFDCA (21 U.S.C. § 321) and is therefore excluded from the TSCA § 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for that use. For example, FDA currently regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460 and as an animal drug (Formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004.
- *Commercial and Consumer Uses, “Personal care products (covered by TSCA)”* under the *“Laundry and dishwashing products; Personal care products (covered by TSCA)”* was removed because, upon further investigation, EPA did not identify any formaldehyde-containing personal care products covered by TSCA. Many personal care products meet the definition of cosmetic, drug, or device under the FFDCA (21 U.S.C. § 321) and are therefore excluded from the TSCA section 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for those uses. As noted in the final scope document for formaldehyde, such products subject to FDA’s jurisdiction were excluded from the final scope and could include eyelash adhesives, hair treatments, moisturizers, mouthwashes, hand cleaning creams, shampoos, conditioners, deodorants, certain nail treatments, perfumes and fragrances, shaving creams, and certain body cleansers containing synthetic detergents. EPA did not identify any formaldehyde-containing personal care products covered by TSCA.
- *Commercial Use, “Food packaging”* under the *“Food packaging; Paper products; Plastic and rubber products; Toys, playground, and sporting equipment”* EPA determined that the “food packaging” meets the definition of food additive under the FFDCA (21 U.S.C. § 321(s)) and is therefore excluded from the TSCA definition of “chemical substance” when manufactured, processed, or distributed in commerce for that use.

- *Commercial Use, Laboratory Chemicals, “specimen preservation, medical samples, mortuary science”* were removed as listed examples because these terms encompass pesticidal uses under FIFRA. Specifically, EPA has identified the following types of products as pesticides that are exempt from the requirements of FIFRA: embalming fluids; products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning; and products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis (see 40 CFR 152.25(c); 53 FR 15952, 15977 (May 4, 1988)). These products meet the definition of “pesticide” under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA section 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for these uses. Other uses of formaldehyde as a laboratory chemical remain within the scope of the TSCA risk evaluation, such as fixative use for slide preparation. Formaldehyde can be used in commercial laboratories for microscope slide preparation and is used to bind proteins in order to make cells or tissues more structurally solid in the short term. For example, an animal cell may be mobile on a glass slide so a fixative that contains formaldehyde could be applied to that slide, so the cell is no longer mobile. EPA has determined that these fixative purposes are in scope because this use is considered non-pesticidal. Use for slide preparation could potentially have a short-term fixative (non-preservation) purpose if there is not also an intent to preserve the tissue for later analysis.

2.2.1 Industries Affected by Activities Determined Not to Be Conditions of Use

Section 2.2.2 of the 2020 Final Scope explained that EPA determined that several uses of formaldehyde were outside the scope of TSCA or were not considered. EPA is making additional clarifications and added details for certain uses outside the scope of TSCA based on public request to explicitly state which uses will not be covered under the draft formaldehyde risk evaluation.

Aquaculture, Hatchery, and Animal Feeds

In the 2020 Final Scope, EPA explained TSCA section 3(2) excludes from the definition of “chemical substance” “any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.” However, EPA did not list specific examples regarding animal feeds or animal drugs. Therefore, EPA is explaining that the use of formaldehyde in animal feed or as an animal drug meets the definition of a “food, food additive, [or] drug,” respectively, under the FFDCA (21 U.S.C. § 321), and is therefore excluded from the TSCA § 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for that use. For example, FDA regulates the use of formaldehyde as a food additive in the manufacture of certain animal feeds under 21 CFR § 573.460, and as an animal drug (Formalin) to control external parasites on hatchery fish and their eggs under 21 CFR § 529.1004.

Embalming and Taxidermy

In the 2020 Final Scope EPA explained TSCA section 3(2) also excludes from the definition of “chemical substance” “any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide.” Products intended for use as a preservative for biological specimens in embalming and taxidermy are considered pesticides under FIFRA. EPA has identified the following types of products as pesticides that are exempt from the requirements of FIFRA: embalming fluids; products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning; and products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis (see 40 CFR 152.25(c); 53 FR 15952, 15977, (May 4, 1988)). Because these products meet the definition of “pesticide” under FIFRA (7 U.S.C. § 136(u)), such formaldehyde-

containing products are therefore excluded from the TSCA section 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for these uses.

Because embalming and taxidermy products intended for preservation of biological specimens are considered pesticides under FIFRA and because FIFRA has a specific exemption for pesticides used for biological preservation under the circumstances described in 40 CFR 152.25(c), uses that fall within the 40 CFR 152.25(c) exemption from regulation under FIFRA are not covered by either the Office of Pesticide Programs formaldehyde registration review under FIFRA or by EPA’s Office of Pollution Prevention and Toxics (OPPT) in this draft TSCA risk evaluation.

2.2.2 Biogenic Sources of Formaldehyde Not Considered as Conditions of Use

EPA does not consider biogenic formation of formaldehyde, such as emissions from trees, plants, and soil microbes, to be conditions of use under TSCA section 3(4). The biogenic formation can significantly contribute to total formaldehyde concentration in ambient air. For purposes of this draft risk evaluation for formaldehyde, EPA considered these as background exposures that are accounted for in the ambient air exposure assessment.

2.3 Certain Combustion Sources and Secondary Formation of Formaldehyde

Formaldehyde can be emitted from many types of combustion. In indoor settings these can include burning candles, tobacco smoke, fireplaces and household appliances. These sources can also include tailpipe emissions (including cars, trucks and boats), emissions from outdoor fires (including wildfires, prescribed fires and agricultural burning), and emissions from industrial sources. Some combustion activities that produce formaldehyde could occur during the manufacture, processing, use or disposal of another chemical substance(s) or mixture(s).

Significant concentrations of formaldehyde are also found in the environment due to secondary formation of the chemical after degradation of other compounds, for example, when a different chemical undergoes chemical reactions in the air and forms formaldehyde.

Because combustion and secondary formation are so abundant and likely result in co-occurring exposures, this draft risk assessment could not practically or reasonably differentiate secondary formation, formation from combustion, and direct released of formaldehyde with certainty for this draft risk evaluation. Secondary formation and combustion are the largest contributor of formaldehyde to ambient air and indoor air concentrations. A full quantitative evaluation of exposure and risk from formaldehyde produced during secondary formation and combustion was not practicable and would impede efforts to conduct a scientifically sound and fit-for-purpose evaluation under TSCA within statutory timeframes. For purposes of this TSCA draft risk evaluation for formaldehyde, EPA considered these as background exposures that are accounted for in the outdoor and indoor air exposure assessment.

2.4 Additions to the Scope Pertaining to Exposure Pathways and Risks Addressed by Other EPA-Administered Statutes

Section 2.6.3.1 of the 2020 Final Scope explained that EPA would not consider certain exposure pathways and risks addressed by other EPA-administered statutes. As announced on June 30, 2021, EPA no longer intends to exclude exposure pathways that are addressed under other EPA-administered statutes or regulatory programs from the scope of TSCA risk evaluations. As further explained in the preamble to the proposed rule, *Procedures for Chemical Risk Evaluation Under the Toxic Substances*

Control Act (88 FR 74292, 74299-74300, October 30, 2023), EPA has reconsidered the text of the relevant statutory provisions, overarching statutory structure and context, and legislative history, and no longer interprets the law to authorize exclusion of exposure pathways from the scope of TSCA risk evaluations because other EPA offices have already or could in the future regulate those chemicals. Accordingly, EPA is no longer excluding from the scope of the Draft Risk Evaluation for Formaldehyde the exposure pathways described below and in Section 2.6.3.1 of the 2020 Final Scope.

Composite Wood Products under TSCA Title VI

EPA stated in the 2020 Final Scope that the Agency had determined that three types of composite wood products (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]), and laminated products currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule (40 CFR part 770, promulgated under TSCA Title VI), would not be included in the scope of the risk evaluation. Since the 2020 Final Scope's publication, EPA no longer intends to exclude exposure pathways that are addressed under other EPA-administered statutes or regulatory programs from the scope of TSCA risk evaluations, therefore all composite wood products, including those regulated under TSCA Title VI, are included in the draft formaldehyde risk evaluation.

EPA has determined that excluding TSCA Title VI regulated composite wood products from the formaldehyde risk evaluation would reduce the comprehensiveness of the risk evaluation and introduce complexities and uncertainties due to the regulated vs. non-regulated materials that may be present in a finished good in indoor environment. However, the Agency also recognizes that allocating exposures due to emissions from finished goods in indoor environments might be difficult due to the monitoring data available for this draft risk evaluation which does not necessarily reflect information after the implementation of TSCA Title VI.

Regulated composite wood products under TSCA Title VI include hardwood plywood, medium density fiberboard, and particle board. Some examples of certain wood product containing COUs may include

- Commercial use in floor coverings; foam seating and bedding products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles; cleaning and furniture care products; leather conditioner; leather tanning, dye, finishing, impregnation and care products; textile (fabric) dyes; textile finishing and impregnating/surface treatment products;
- Commercial use in construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles;
- Consumer use in floor coverings; foam seating and bedding products; cleaning and furniture care products; furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles;
- Consumer use in construction and building materials covering large surface areas, including wood articles; construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles.

Exposure Pathways from Ambient Air, Drinking Water, Onsite Releases to Land, Disposal and Soil

The draft formaldehyde risk evaluation does not exclude from its scope exposure pathways from ambient air, drinking water, onsite releases to land, disposal and soil as described in Section 2.6.3.1 of the 2020 Final Scope document. The conceptual model depicted in Figure 2-15 of the 2020 Final Scope document has been updated in Figure 1-7 of the *Draft Human Health Risk Assessment for Formaldehyde* to reflect the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial, commercial, and consumer uses of formaldehyde that EPA considered in the draft risk evaluation.

2.5 Clarification Regarding Consideration of Formalin and Paraformaldehyde in the Draft Risk Evaluation

Formalin

Formaldehyde is a gas that is distributed in solution as formalin. Formalin is a formulation of formaldehyde in aqueous solution and is composed of three components—formaldehyde, methanol, and water. It occurs as a colorless liquid at room temperature. Therefore, formalin was assessed as a part of the formaldehyde risk evaluation under the TSCA COUs as listed in Table 2-1. It should be noted that certain uses of formalin, such as the use as an animal drug as defined in the FFDCA to control external parasites on hatchery fish and their eggs, are excluded from the TSCA section 3(2) definition of “chemical substance” and therefore not included in the Draft Risk Evaluation for Formaldehyde.

Paraformaldehyde

Paraformaldehyde was not assessed since it is considered a different chemical substance with a different CAS number (30525-89-4), and not prioritized or included in the *Final Scope of the Risk Evaluation for Formaldehyde CASRN 50-0-0*.

Appendix A Regulatory History

The chemical substance, formaldehyde, is subject to federal and state laws and regulations in the United States (Table_Apx A-1 and Table_Apx A-2). Regulatory actions by other governments, tribes, and international agreements applicable to formaldehyde are listed in Table_Apx A-3. EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to formaldehyde. This appendix contains the compiled information from available federal, state, international, and other government sources.

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Formaldehyde is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924 , December 30, 2019). Designation of formaldehyde as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Formaldehyde manufacturing (including importing), processing and use information is reported under the CDR rule (85 FR 20122 , April 9, 2020).
Toxic Substances Control Act (TSCA) – Section 8(d)	Provides EPA with authority to issue rules requiring manufacturers (including importers), processors, and distributors of a chemical substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies. EPA’s Health and Safety Data Reporting Rule at 40 CFR part 716 generally requires such submissions for manufacturers (including importers) and (if specified) processors of substances covered by part 716.	29 health and safety studies received for Formaldehyde (2021) (U.S. EPA, ChemView . Accessed February 5, 2024).
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical	23 risk reports received for formaldehyde, or containing information related to formaldehyde were received between 1989 and 2011. (U.S. EPA, ChemView ,

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	substance or mixture presents a substantial risk of injury to health or the environment.	Accessed February 5, 2024). Link to the 8(e) submission crosswalk HERE .
Toxic Substances Control Act (TSCA) – Subchapter 6	TSCA Title VI sets formaldehyde emission standards for composite wood products (<i>i.e.</i> , hardwood plywood, medium density fiberboard, and thin-medium density fiberboard) and requires that any component parts or finished goods fabricated with composite wood products use compliant panels that have met the emission standards and been tested/certified by an EPA recognized TSCA Title VI third party certifier. The TSCA Title VI program also has provisions for labeling, recordkeeping, import certification, and accreditation/third party certification oversight and annual reporting on the regulated composite wood products manufactured by mills.	TSCA Title VI sets formaldehyde emission standards for composite wood products (<i>i.e.</i> , hardwood plywood, medium density fiberboard, and thin-medium density fiberboard) and requires third party certification, oversight, and annual reports to be submitted to EPA annually on all panel manufacturing under the TSCA Title VI program both domestically and internationally (40 CFR 770).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	EPCRA Section 313 – also known as the Toxic Release Inventory (TRI) – requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (<i>e.g.</i> , quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (<i>i.e.</i> , air, land and water).	Formaldehyde is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. EPA assesses the whole formulation of pesticide products including active ingredients which have pesticidal effects and inert ingredients that do not. EPA keeps lists of inert	Formaldehyde was registered as an antimicrobial, conventional chemical on January 25, 1967. In June 2008 EPA published a reregistration eligibility decision for formaldehyde and paraformaldehyde (Case 0556; EPA Document 739-R-08- 004). Formaldehyde is currently

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	ingredients that have been approved for use in pesticide products distinguishing between those that have been approved for use on food and those that have not. Pesticide products may only be registered if, among other things, they do not cause “unreasonable adverse effects on the environment.” Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	under registration review, and the final work plan has been published (EPAHQ-OPP-2015-0739).
Federal Food, Drug, and Cosmetic Act (FFDCA) – Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to establish tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for pesticide residues (including inert ingredients) on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is “safe.” Section 408(b) of the FFDCA defines “safe” to mean a reasonable certainty that no harm will result from aggregate exposures (which includes dietary exposures from food and drinking water as well as nonoccupational exposures) to the pesticide. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation under FFDCA section 408(d) or (e). In the absence of a tolerance or an exemption from tolerance, or where pesticide residues in food exceed an existing tolerance limit, a food containing that pesticide residue is considered adulterated and may not be distributed in interstate commerce.	Formaldehyde is no longer exempt from the requirement of a tolerance (the maximum residue level that can remain on food or feed commodities under 40 CFR Part 180, Subpart D).
Clean Air Act (CAA) – Section 111(b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution, which may	EPA has established NSPS for a number of source categories that regulate emissions of Formaldehyde to air. (See https://www.epa.gov/stationary-sources-air-pollution/new-source-performance-standards).

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	reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction (BSER) which (taking into account the cost of achieving reductions and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	
Clean Air Act (CAA) – Section 112(b)	Contains the original list of 189 hazardous air pollutants (HAPs) that Congress added in 1990. Under 112(c) of the CAA, EPA must identify and list source categories that emit listed HAPs and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990, EPA has both removed HAPs from and added HAPs to the original list.	Formaldehyde is listed as a HAP (42 U.S.C 7412).
Clean Air Act (CAA) – Section 112(d)	Directs EPA to establish, by rule, National Emission Standards for Hazardous Air Pollutants (NESHAPs) for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). For major sources, the standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For areas sources, the standards must require generally achievable control technology (GACT) though may require MACT. Section 112(d)(6) requires EPA to review, and revise, as necessary, (taking into account developments in practices, processes and control technologies) the emission standards every 8 years.	EPA has established NESHAPs for a number of source categories that emit Formaldehyde to air. (See https://www.epa.gov/stationary-sources-air-pollution/national-emission-standards-hazardous-air-pollutants-neshap-8)
Clean Air Act (CAA) – Section 112(f)	Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) NESHAP that require maximum achievable control technology (MACT) and to determine if additional standards are	EPA has promulgated a number of Risk and Technology Review (RTR) NESHAP and will do so, as required, for the remaining source categories with NESHAP.

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	needed to reduce remaining risks; this is required within 8 years of promulgating the NESHAP.	
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all volatile organic compound (VOC) emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require “best available controls.” In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	Formaldehyde is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Formaldehyde has a reactivity factor of 8.97 g O ₃ /g VOC.
Clean Water Act (CWA) – Section 311(b) (2)(A) and 501(a) of the Federal Water Pollution Control Act.	Requires EPA to develop, promulgate, and revise as may be appropriate, regulations designating as hazardous substances, other than oil, which, when discharged present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.	Formaldehyde is a designated hazardous substance in accordance with Section 311(b) (2)(A) of the Federal Water Pollution Control Act (40 CFR Section 116.4 , see 43 FR 10474 (March 13, 1978)).
Safe Drinking Water Act (SDWA) – Section 1412(b)	Every 5 years, EPA must publish a list of contaminants that: (1) are currently unregulated, (2) are known or anticipated to occur in public water systems (PWSs) and (3) may require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	Formaldehyde was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (CCL) (74 FR 51850 , October 8, 2009) and (81 FR 81099 , November 17, 2016).
Resource Conservation and Recovery Act (RCRA) – Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Formaldehyde is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U122 (40 CFR 261.33). Formaldehyde is also listed as part of various groups of chemicals in Appendix VII to Part 261 – Basis for Listing Hazardous Waste as K009, K010, K038, K040, K156, and K157 (40 CFR Appendix VII to Part 261). Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under

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		the AutoAlliance International, Inc. of Flat Rock Michigan and DamlierChrysler Corporation, Jefferson North Assembly Plant, Detroit Michigan entries which permit a TCLP extraction sample not-to-exceed limit of 84.2 mg/L of formaldehyde in their leachate extract, and a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,380. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Eastman Chemical Company – Texas Operations which permits a bottom ash leachable concentration at 347 mg/L. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company Dearborn Assembly Plant which permits a TCLP extraction sample not to exceed 80 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 700 mg/kg, and a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,400. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Kansas City Assembly Plant which permits a TCLP extraction sample not to exceed 343 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 6880 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Michigan Truck Plant and Wayne Integrated Stamping and Assembly Plant which

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 689 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,380. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Ford Motor Company, Wixom Assembly Plant which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 689 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Assembly Plant which permits a TCLP extraction sample not to exceed 84 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to exceed 700 mg/kg, and a maximum allowable groundwater concentration (µg/L) of 1,390. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation, Flint Truck and Hamtramck facilities which permit TCLP extraction samples not to exceed 63 mg/L of formaldehyde in their leachate extract and total concentrations of formaldehyde not to exceed 535 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Janesville Truck Assembly Plant which permits a TCLP extraction sample not to exceed 43 mg/L of formaldehyde in their leachate extract, a total concentration of formaldehyde not to

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		exceed 540 mg/kg, and a maximum allowable groundwater concentration (mg/L) of 0.950. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Lansing Car Assembly – Body Plant which permits a TCLP extraction sample not to exceed 672 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 2100 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the General Motors Corporation Pontiac East – Body Plant which permits a TCLP extraction sample not to exceed 63 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 535 mg/kg. Formaldehyde is also listed as part of Appendix IX to Part 261 – Wastes Excluded from Non-Specific Sources under the Trigen/Cinergy-USFOS of Lansing LLC at General Motors Corporation, Lansing Grand River which permits a TCLP extraction sample not to exceed 84.2 mg/L of formaldehyde in their leachate extract and a total concentration of formaldehyde not to exceed 689 mg/kg.
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances, in addition to those referred to in section 101(14) of CERCLA, those elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they	Formaldehyde is a hazardous substance under CERCLA. Releases of formaldehyde in excess of 100 pounds must be reported (40 CFR 302.4).

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	have knowledge of a release of a hazardous substance above the reportable quantity threshold. CERCLA Hazardous substances listed under 40 CFR Table 302.4 are subject to EPCRA Section 304 notification requirements.	
Superfund Amendments and Reauthorization Act (SARA) –	Amendments made several important changes to CERCLA, for example: requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the Superfund program and provides new enforcement authorities and settlement tools.	Formaldehyde is listed as number 224 scoring 605 points on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
Other federal regulations		
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics, except residues of pesticides in food are regulated by EPA under FFDCA section 408 (discussed above where applicable).	The FDA regulates formaldehyde as an indirect food additive under its food additive and GRAS regulations (21 CFR 175.105, 175.210, 175.300, 176.170, 176.180, 176.200, 176.210, 177.1460, 177.1900, and 177.2480). Formaldehyde is also listed as an adhesive used in food packaging at 21 CFR 175.105. Formaldehyde is regulated by FDA as a food additive used in the manufacture of animal feeds in accordance with 21 CFR 573.460. Formalin (an aqueous solution containing approximately 37% by weight of formaldehyde gas, U.S.P.) is regulated by FDA as a new animal drug when used to control external parasites on hatchery fish and their eggs. 21 CFR 529.1004. Formaldehyde is also listed as an “Inactive Ingredient for approved Drug Products” by FDA with an established limit of 0.2% Weight/Weight (W/W) on the amount of formaldehyde that can be present a solution, and 0.27% W/W on the amount of formaldehyde that

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		can be present in an emulsion or cream (FDA Inactive Ingredient Database, Accessed April 10, 2019).
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous, or the nature of the hazard is such that labeling is not adequate to protect consumers.	Under the Federal Hazardous Substance Act, Section 1500.83(a)(31), formaldehyde and products containing 1% or more formaldehyde are listed as “strong sensitizer” substances by CPSC (16 CFR 1500.13).
Occupational Safety and Health Act (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	OSHA issued occupational safety and health standards for formaldehyde that included a PEL of 0.75 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1048(c)(1)). OSHA has separate sections of the CFR for formaldehyde PELs for shipyard and construction employment; however, those sections reference the generic formaldehyde PEL at 1910.1048(c)(1). 10 CFR 851.23 , Worker Safety and Health Program, requires the use of the 2005 (updated in 2016) American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) if they are more protective than the OSHA PEL.
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	The Department of Transportation (DOT) has designated Formaldehyde solutions as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR 172.101(g)).

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels (AAL) of Formaldehyde in New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants) is 1.3 (µg/m³) for a 24-hour AAL, 0.88 (µg/m³) for an annual AAL, 0.015 lbs/day for a 24-hour de-minimis, and 5.6 lbs/year for an annual de-minimis. Acceptable Ambient Levels (AAL) of Formaldehyde in Rhode Island is 50 (µg/m³) for a 1-hour AAL, 40 (µg/m³) for a 24-hour AAL, and 0.08 lbs/year for an annual (Air Pollution Regulation No. 22). As well, the requirement for registration has a threshold of 9 lbs/year as a minimum quantity for air emissions of formaldehyde; any exceedance of this minimum would trigger a reporting requirement the following year (Air Pollution Regulation No. 22.4.2(c)).
State Drinking Water Standards and Guidelines	Formaldehyde is listed in the groundwater: residential and nonresidential part 201 generic cleanup criteria and screening levels in Michigan with the following levels: residential drinking water criteria of 1,300 ppm, nonresidential drinking water criteria of 3,800 ppm, groundwater surface water interface criteria of 120 ppm, residential groundwater volatilization to indoor air inhalation criteria of 63,000 ppm, nonresidential groundwater volatilization to indoor air inhalation criteria of 360,000 ppm, and a water solubility of 550,000,000 ppm (Mich. Admin. Code r.299.44 and r.299.49, 2017).
State PELs	California (PEL of 0.75 ppm and a STEL of 2 (Cal Code Regs. Title 8, § 5155 and Cal Code Regs. Title 8, § 5217)) Hawaii PEL: 0.75 ppm and a STEL of 2 for 15 minutes (Hawaii Administrative Rules Section 12-60-50 which refer to 29 CFR § 1910.1048 as a proxy for formaldehyde).
State Right-to-Know Acts	Formaldehyde is found in the following State Right to-Know Acts: Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (8:59 N.J. Admin. Code § 9.1) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing Formaldehyde, including Maine (38 MRSA Chapter 16-D), Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407), Oregon (Toxic-Free Kids Act, Senate Bill 478, 2015), Vermont (18 V.S.A § 1776) and Washington State (Wash. Admin. Code 173-334-130).
Volatile Organic Compound (VOC) Regulations for Consumer Products	Many states regulate Formaldehyde as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include composite wood products, aerosol coating products, as well as antiperspirant and deodorant (among other products). Composite Wood Products (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 7.5, Section 93120) and Aerosol Coating Product in California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 3 and 17 CCR 93120), Antiperspirant and Deodorant in Delaware (Adm. Code Title 7, 1141),

State Actions	Description of Action
	Antiperspirant and Deodorant in Illinois (35 Adm Code 223), Antiperspirant and Deodorant in New Hampshire (Env-A 4100) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting.
Other	California listed formaldehyde on Proposition 65 in 1988 due to cancer. (Cal Code Regs. Title 27, § 27001). Formaldehyde is listed as a Candidate Chemical under California’s Safer Consumer Products Program (Health and Safety Code § 25252 and 25253). California issued a Health Hazard Alert for formaldehyde (Hazard Evaluation System and Information Service, 2016). Massachusetts designated formaldehyde as a Higher Hazard Substance requiring reporting starting in 2012 (301 CMR 41.00).

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by Other Governments and Tribes

Country/ Organization	Requirements and Restrictions
Canada	Formaldehyde is on the Canadian List of Toxic Substances (CEPA, 1999 Schedule 1). A Priority Substances List (PSL) Assessment determined that formaldehyde is primarily used in the production of resins and fertilizers and enters the Canadian environment from direct human sources such as automotive and other fuel combustion and industrial on-site uses. Secondary formation occurs by the oxidation of natural and anthropogenic organic compounds present in air. The PSL Assessment report for formaldehyde determined that formaldehyde contributes to photochemical formation of ground-level ozone; and therefore, continued and improving monitoring at sites likely to release formaldehyde is desirable; especially those sites with industrial uses for resins and for fertilizers as well as releases from pulp and paper mills. The PSL assessment also recommended continued investigation into options to reduce indoor air exposure to formaldehyde (Environment Canada Database, Accessed February 23, 2024.) Other regulations include: • Canada’s National Pollutant Release Inventory (NPRI). • Off Road Compression-Ignition Engine Emission Regulations (SOR/2005-32). • CCPA and Governments of Canada, Ontario, and Alberta Memorandum of Understanding for Environmental Protection Through Action Under CCPA Responsible Care (MOU, August 14, 2013). • Environmental Emergency Regulations (SOR/2003-307). • On-Road Vehicle and Engine Emission Regulations (SOR/2003-2). • Off-Road Small Spark-Ignition Engine Emission Regulations (SOR/2003-355).

Country/ Organization	Requirements and Restrictions
	Formaldehyde Emissions from Composite Wood Products Regulations (SOR/2021-148)
European Union	Formaldehyde is listed on the European Chemicals Agency (ECHA) Inventory (EC Number 200-001-8) and the European Union (EU): Classification, Labelling and Packaging (CLP) Harmonized Classification (index number 605-001-00- 5). Formaldehyde was evaluated under the 2013 Community rolling action plan (CoRAP) under regulation (EC) No1907/2006 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals (European Chemicals Agency (ECHA) database, Accessed February 5, 2024). On July 2023, the European Union revised the restrictions under REACH with respect to formaldehyde and formaldehyde releasers, and established limits for formaldehyde releases of 0.062 mg/m³ for furniture and wood-based articles and of 0.080 mg/m³ for articles other than furniture and wood-based articles. In addition, the regulations established a maximum concentration of formaldehyde in the interior of in road vehicles of 0.062 mg/m³. (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1464&qid=1690878840638)
Australia	Formaldehyde was assessed under a Priority Existing Chemical designation (designated March 5, 2002) in response to occupational and public health concerns. The main industrial use of formaldehyde is for the manufacture of formaldehyde-based resins, which are widely used in a variety of industries, predominantly the wood industry. Formaldehyde is also used directly or in formulations in a number of industries including medicine-related industries (such as forensic/hospital mortuaries and pathology laboratories), embalming in funeral homes, film processing, textile treatments, leather tanning, and a wide range of personal care and consumer products. The concentrations of formaldehyde in these products range from 40%, such as in embalming and film processing solutions, to < 0.2%, such as in the majority of cosmetics and consumer products (NICNAS, 2006, Priority Existing Chemical Assessment Report No. 28 for Formaldehyde, Accessed February 5, 2024).
Japan	Formaldehyde is regulated in Japan under the following legislation: - Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) - Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (Pollutant Release and Transfer Registers & Safety Data Sheet Law (PRTR-SDS Law)) - Industrial Safety and Health Act (ISHA) - Air Pollution Control Law - Water Pollution Control Law - Soil Contamination Countermeasures Act - Poisonous and Deleterious Substances Control Act - Act on the Control of Household Products Containing Harmful Substances

Country/ Organization	Requirements and Restrictions
	• Food Sanitation Act • Fire Service Act (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHIRP]. Accessed February 5, 2024).
Basel Convention	B3010 (urea, phenol, and melamine formaldehyde resins) are listed as a category of waste under the Basel Convention . Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	B3010 (urea, phenol, and melamine formaldehyde resins) are listed as a category of waste subject to the Amber Control Procedure under Council Decision C (2001) 107/Final .
World Health Organization (WHO)	WHO has not established a tolerable daily intake for formaldehyde; however, did note that the average daily intake of formaldehyde is 0.02 mg/day for outdoor air; 0.05–2 mg/day for indoor conventional buildings, <1–10 mg/day for buildings without sources of formaldehyde, 0.2–0.8 mg/day for workplaces without occupational use of formaldehyde, 4 mg/day for work places using formaldehyde, and 0–1 mg/day for environmental tobacco smoke (smoking 20 cigarettes a day corresponds with an intake of 1 mg/day of formaldehyde). The average daily intake of formaldehyde in drinking water is generally 0.2 mg/day and the quantity of formaldehyde generally ingested in food (contingent on the meal composition) may range from 1.5 to 14 mg/day. (Environmental Health Criteria (EHC) Monograph 89, 1989).
Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, Latvia, New Zealand, Norway, People’s Republic of China, Poland, Romania, Singapore, South	Occupational exposure limits for Formaldehyde (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database . Accessed February 5, 2024).

Country/ Organization	Requirements and Restrictions
Africa, South Korea, Spain, Sweden, Switzerland, The Netherlands, United Kingdom	