

# Formaldehyde TSCA Risk Evaluation Consortium



# Why is it Important to Understand and Engage in the TSCA Process?

In June 2016, a bipartisan majority in Congress amended the Toxic Substances Control Act (TSCA) to reform the regulation of chemicals in commerce in the United States. The amendments provide the U.S. Environmental Protection Agency (EPA) with expanded authority to:

1. Subject all new and existing chemicals to an EPA safety review;
2. Focus on chemicals that are the highest priorities for full risk-based safety assessments;
3. Require additional health and safety testing of chemicals;
4. Make an affirmative safety determination on conditions of use associated with a chemical; and
5. Identify and implement risk management options for any use determined to present an unreasonable risk to human health or the environment.

A cornerstone of the TSCA risk evaluation process is the engagement and involvement of the chemical industry to provide relevant human health data, animal laboratory study data, exposure data, and information to inform EPA's risk evaluations. The chemical industry is fully committed to supporting EPA's effective and efficient implementation of TSCA. In order to do so, **it is critical our industry provides EPA with the most relevant, highest-quality information.**

Our participation will help ensure EPA is empowered to conduct thorough evaluations based on hazard, use, and exposure. The chemical industry's growth, technological innovation, and global competitiveness depends upon the active participation of stakeholders

**The recently amended TSCA provides the framework for one of the premier regulatory systems to assess and evaluate chemical risk. TSCA gives EPA the authority to regulate chemicals in commerce that are the highest priority and manage any identified unreasonable risks.**

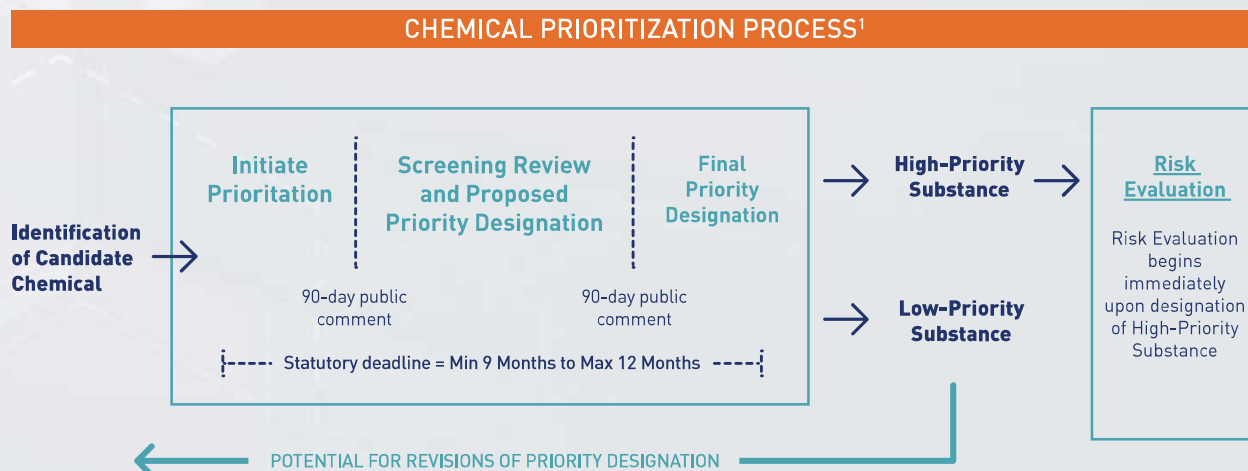
# What is the Chemical Prioritization Process and How Long Does it Take?

Prioritization is the initial step in EPA's TSCA process of evaluating the safety of existing chemicals. On March 21, 2019, EPA published in the federal register the next set of candidate chemical substances that will undergo review by its TSCA risk evaluation program. This announcement formally begins the prioritization process, and starts a 9- to 12-month statutory time frame during which the Agency will propose and finally designate 20 chemical substances as high priority. There are two 90-day public comment periods to submit relevant information.

Formaldehyde was identified as a high-priority candidate chemical for TSCA risk evaluation. This represents an important milestone in the TSCA risk evaluation

process and affords chemical industry stakeholders the opportunity to collaborate and provide initial data and information to inform the prioritization process. The current comment period for formaldehyde is open until June 19, 2019.

It is important to note that a designation of formaldehyde as a high-priority chemical "does not constitute a finding of risk" and should not be cause for concern. A high-priority designation simply means the EPA has nominated formaldehyde for further risk evaluation.



<sup>1</sup> [www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation](http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation)



# What Does a Formaldehyde TSCA Risk Evaluation Mean for Your Business?

In conducting a risk evaluation under TSCA, EPA will identify “circumstances” that constitute “conditions of use” for formaldehyde. This means that the Agency will focus risk evaluations, and any corresponding risk management, on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen.

In other words, the TSCA risk evaluation process will focus on the lifecycle of the chemical substance. If EPA’s TSCA risk evaluation identifies conditions of use of formaldehyde that present an unreasonable risk, EPA must evaluate and could implement

risk management options to restrict or eliminate formaldehyde’s use in those applications. **This could lead to deselection of formaldehyde from critical applications.** Additionally, the results of EPA’s risk evaluation may also lead to modifications on permitting, procurement, and regulatory requirements at the federal and state level, as well as further market deselection pressures. It is critically important that up-to-date scientific information on potential hazard and relevant consumer exposure underlie the risk evaluation.

See below for all the ways formaldehyde is already adequately regulated.

EPA has implemented several laws and regulations that govern the use of formaldehyde, including

- ♦ TSCA Title VI gives EPA authority to regulate formaldehyde emissions from composite wood products and TSCA Section 5(a)(2) regulates significant new uses of formaldehyde.
- ♦ The Resource Conservation and Recovery Act (RCRA) gives EPA the authority to control hazardous waste from the “cradle-to-grave.” This includes the generation, transportation, treatment, storage, and disposal of formaldehyde.
- ♦ Clean Water Act (CWA) Section 311(b)(2)(A) regulates discharges of substances, including formaldehyde.
- ♦ The Clean Air Act (CAA) allows EPA to set limits on certain air pollutants, and formaldehyde is regulated pursuant to national emission standards under Section 112. Section 202(1) of CAA also allows EPA to regulate emissions of formaldehyde from highway vehicles and non-road equipment.

The U.S. Department of Labor’s Occupational Safety and Health Administration (OSHA) has standards for workplace exposures to formaldehyde. These comprehensive health standards include limits on permissible exposures, requirements for monitoring employee exposures in the workplace, protective measures – including engineering controls, medical surveillance and communication – and training about hazards.

Three agencies – EPA, Consumer Product Safety Commission (CPSC), and U.S. Department of Housing and Urban Development (HUD) – have addressed indoor air exposure to formaldehyde. HUD has standards that limit formaldehyde emissions from wood products for use in manufactured housing. CPSC determined that independent CPSC action was unnecessary given the voluntary actions and low levels of formaldehyde emissions.

The Food and Drug Administration (FDA) has reviewed the safety of formaldehyde and approved its use as an indirect food additive.

# What is the TSCA Risk Evaluation Process and How Long Does it Take?

Risk Evaluation is the second step in the TSCA process, following Prioritization. The purpose of risk evaluation is to determine whether formaldehyde presents an unreasonable risk to human health or

the environment, under the conditions of use assessed by EPA. The scope of a risk evaluation will include evaluation of the relevant hazards, exposures, and conditions of use for formaldehyde.<sup>2</sup>



While the TSCA risk evaluation process will span approximately three years, to be fully considered, relevant data to inform the risk evaluation should be submitted within the first 18 months of the process. During this time EPA will identify and evaluate the circumstances (i.e. conditions of use) under which formaldehyde is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.

EPA will then evaluate those conditions of use to determine if there is any unreasonable risk. It will be critical for formaldehyde manufacturers, members

of the value chain including downstream users to engage in the process to provide EPA information regarding potential formaldehyde exposures associated with their products or uses. Without input from the chemical industry and its downstream users of formaldehyde, EPA may rely on modeling or anecdotal exposure information that may not accurately reflect real world exposures or how products are used or manufactured. **It is imperative that formaldehyde stakeholders be actively involved in this process to ensure that EPA's formaldehyde risk evaluation is based on real quantitative evidence.**

<sup>2</sup> [www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca)

# TSCA Risk Evaluation Process Timeline.

PROJECTED COMPLETION	TSCA RISK EVALUATION ELEMENT
March 21, 2019	<ul style="list-style-type: none"> <li>» Initiation of 20 TSCA High-Priority Candidates</li> <li>» 90-Day Public Comment Period</li> </ul>
By December 2019	<ul style="list-style-type: none"> <li>» Final TSCA High-Priority Designation</li> <li>» The Official Start of the Risk Evaluation Clock</li> <li>» Publication of a Preliminary List that Identifies Manufacturers</li> <li>» Published at the time of Final High-Priority Designation</li> <li>» 30-Day Public Comment Period</li> </ul>
By March 2020	<ul style="list-style-type: none"> <li>» Draft TSCA Scoping Document (Conditions of Use Identified)</li> <li>» 90 Days After Final High-Priority Designation</li> <li>» 45-Day Public Comment Period</li> </ul>
By July 2020	<ul style="list-style-type: none"> <li>» Final TSCA Scoping Document</li> <li>» 180 Days After Final High-Priority Designation</li> <li>» Publication of a Final List of Manufacturers</li> <li>» Responsible for Payment of TSCA Risk Evaluation Fees</li> <li>» Published Concurrently with the Final Scoping Document</li> </ul>
By November 2020	<ul style="list-style-type: none"> <li>» Payment of TSCA Risk Evaluation Fees</li> <li>» 120 Days After Final Scoping Document</li> </ul>
By December 2021	<ul style="list-style-type: none"> <li>» Draft TSCA Risk Evaluation</li> <li>» No deadline for release</li> <li>» 60-Day Public Comment Period</li> </ul>
By December 2022	<ul style="list-style-type: none"> <li>» Final TSCA Risk Evaluation</li> </ul>

# What is the Cost of a TSCA Risk Evaluation?

**Manufacturers and importers of formaldehyde will be required to equally share payment of a \$1,350,000 fee for EPA to conduct the risk evaluation.**

Full payment to EPA will be due within 120 days of EPA publishing the final scoping document for the risk evaluation.

## Estimated Costs (Direct and Indirect) Associated with an Average Chemical Risk Evaluation

RISK EVALUATION ACTIVITY	ESTIMATED COST
Risk Evaluation: Databases	\$147,000
Risk Evaluation: Hazard Assessment	\$1,008,000
Risk Evaluation: Exposure Assessment	\$1,038,000
Risk Evaluation: Scoping	\$235,000
Risk Evaluation: Draft Evaluation	\$502,000
Risk Evaluation: Peer Review & Responding to Comment	\$230,000
Risk Evaluation: Final Evaluation	\$329,000
TOTAL	\$3,884,000

# ACC Center for Chemical Safety: Formaldehyde TSCA Risk Evaluation Consortium.

For years, several producers, suppliers and users of formaldehyde and formaldehyde products, as well as trade associations representing key formaldehyde applications, have organized as members of the ACC Formaldehyde Panel (the Panel) to conduct scientific research, regulatory and legislative advocacy, and educational outreach. The Panel has invested millions of dollars in conducting and communicating scientific research, including:

- Evaluating potential associations between formaldehyde and cancers;
- Quantifying thresholds for formaldehyde exposure; and
- Understanding differences between formaldehyde found in the environment and formaldehyde produced by normal body processes.

This work has provided critical information for regulatory and scientific policy decision-making in the U.S. and abroad.

During the TSCA process, chemical manufacturers, processors, importers and downstream users will have opportunities to provide input to EPA and may be subject to Agency requests for additional information. Given the implications of a TSCA risk evaluation for current and future emission

standards, permit requirements, and the overall use of formaldehyde, stakeholders must play an active role in the evaluation process and maximize all the opportunities to provide input to EPA.

**In an effort to share costs and promote efficiency, formaldehyde stakeholders are forming a consortium to collaborate on the development of comments, generate relevant data and information, and meet with EPA to inform the TSCA risk evaluation.**

The American Chemistry Council (ACC) Center for Chemical Safety will serve as the scientific, technical and advocacy hub for providing information and building the consortium to help formaldehyde stakeholders navigate the TSCA risk evaluation process.

## Scope of ACC Formaldehyde TSCA Risk Evaluation Consortium Activities

- Assembly of existing toxicology, epidemiology, mechanistic and exposure data and other scientifically relevant information to inform the scope of the risk evaluation.



- Generation of relevant new data to inform the risk evaluation.
- Development of a targeted risk evaluation in accordance with EPA TSCA guidance.
- Development of comments for submission to EPA on relevant risk evaluation documents.
- Coordination on the development and/or use of Consortium-generated data.
- Payment of fees to EPA associated with the risk evaluation.
- Coordinated review and comment on all draft risk evaluation documents.
- Access to expertise in risk evaluation, chemical management, and TSCA process.
- Real-time monitoring and analysis of news, and legislative and regulatory developments associated with the risk evaluation.
- Dedicated secure website to share relevant risk evaluation information.
- Coordinated science advocacy and engagement with relevant regulatory agencies to support a science-based risk evaluation process.
- Focused stakeholder collaboration on risk evaluation science.

### **Benefits of Participation in ACC Formaldehyde TSCA Risk Evaluation Consortium**

- Dedicated staff with extensive experience managing all aspects of the risk evaluation process, including:
  - ◊ Legal counsel for antitrust guidance and legal support of general consortium operations.
  - ◊ Toxicologist to lead consortium, manage budget, review scientific information and provide scientific advisory role.
  - ◊ Communications specialist to address media inquiries, monitoring and proactive communications.
  - ◊ Coordinator to provide administrative support and data research.
- Access to third-party scientific experts to provide guidance and expertise on specific risk evaluation areas.
- Ability to leverage staff and financial resources to accomplish risk evaluation activities.

# FAQS

## **Why is a risk-based determination by EPA so important to my business?**

EPA uses risk-based screening and evaluation to determine the probability that a chemical will cause harm based on its hazard, use, and exposure to humans or the environment. It is important to understand the difference between risk and hazard in relation to chemicals. Hazard is the ability of a chemical to cause harm under any circumstance. Risk is the probability that a chemical will cause harm based on its hazard, use, and exposure. Risk-based screening and evaluations must take all of this into consideration.

## **What is a systematic review?**

EPA defines systematic review as the “structured process of identifying, evaluating, and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process.” Systematic reviews are thorough assessments designed to provide transparency and scientific credibility in the evaluation process.

## **What type of “scientific evidence” does EPA require?**

TSCA requires the use of the best available science, meaning that information must be of the highest quality in order to be

included in the review. This type of evidence includes the hazard and exposure potential of the chemical substance; persistence and bioaccumulation information; potentially exposed or susceptible subpopulations; the conditions of use or significant changes in the conditions of use of the chemical substance; and the volume or significant changes in the volume of the chemical substance manufactured or processed.

## **What does weight of the scientific evidence mean?**

This refers to how the agency gives the greatest weight (or importance) to evidence that comes from the strongest and most relevant studies.

## **What conditions of use will EPA choose for formaldehyde?**

TSCA provides EPA with the discretion to identify a chemical’s intended, known, and reasonably foreseen conditions of use. Those cannot be based on speculations, anecdotal reports, or conjecture. EPA has the authority to evaluate the conditions of use and to take measures to impose appropriate controls to protect human health and the environment. EPA will clearly identify the conditions of use it will focus on during its risk evaluation at the onset of the process by publishing a scoping document.



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