

## CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Risk Evaluation Rule

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The Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA) requires EPA conduct risk evaluations on existing chemicals to determine if the chemical presents an unreasonable risk to health or the environment, under the conditions of use. While EPA ultimately determines which chemicals undergo evaluation, TSCA does allow manufacturers, of a given chemical or category of chemicals, to request EPA conduct a risk evaluation on the chemical or category. Requests for an EPA-conducted risk evaluation will be considered following the completion of this CDX form.

EPA risk evaluations are required to be conducted on chemicals under their conditions of use, so the requesting manufacturer(s) must request the condition(s) of use for which the risk evaluation be conducted, with the understanding that EPA may determine other uses are necessary to consider in the risk evaluation. Conditions of use, as defined by TSCA, are the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

The requester must provide a list of all the necessary existing information that is relevant to whether the chemical substance, under the condition(s) of use identified the manufacturer(s), presents an unreasonable risk of injury to health or the environment, that will allow the Agency to complete the risk evaluation. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s). The request does not need to include copies of the information; citations are sufficient, if the information is publicly available. The request must include or reference all the information on the health and environmental hazard(s), human and environmental exposure(s), and exposed population(s) relevant to the conditions of use identified in the request. At a minimum, this must include all the following as relevant to the circumstances identified:

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the manufacturer(s) believes is relevant to the EPA risk evaluation;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the

- The chemical substance's hazard and exposure potential;
- The chemical substance's persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations which the manufacturer(s) believes is relevant to the EPA risk evaluation;
- Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's production volume or significant changes in production volume; and
- Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

The request must include a commitment to provide to EPA any referenced information upon request. The request may also include any information that will inform EPA's determination as to whether restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment and that as a consequence, the request is entitled to be preferentially considered for a risk evaluation.

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