Trichloroethylene (TCE): Risk Evaluation and Risk Management under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Public Webinar
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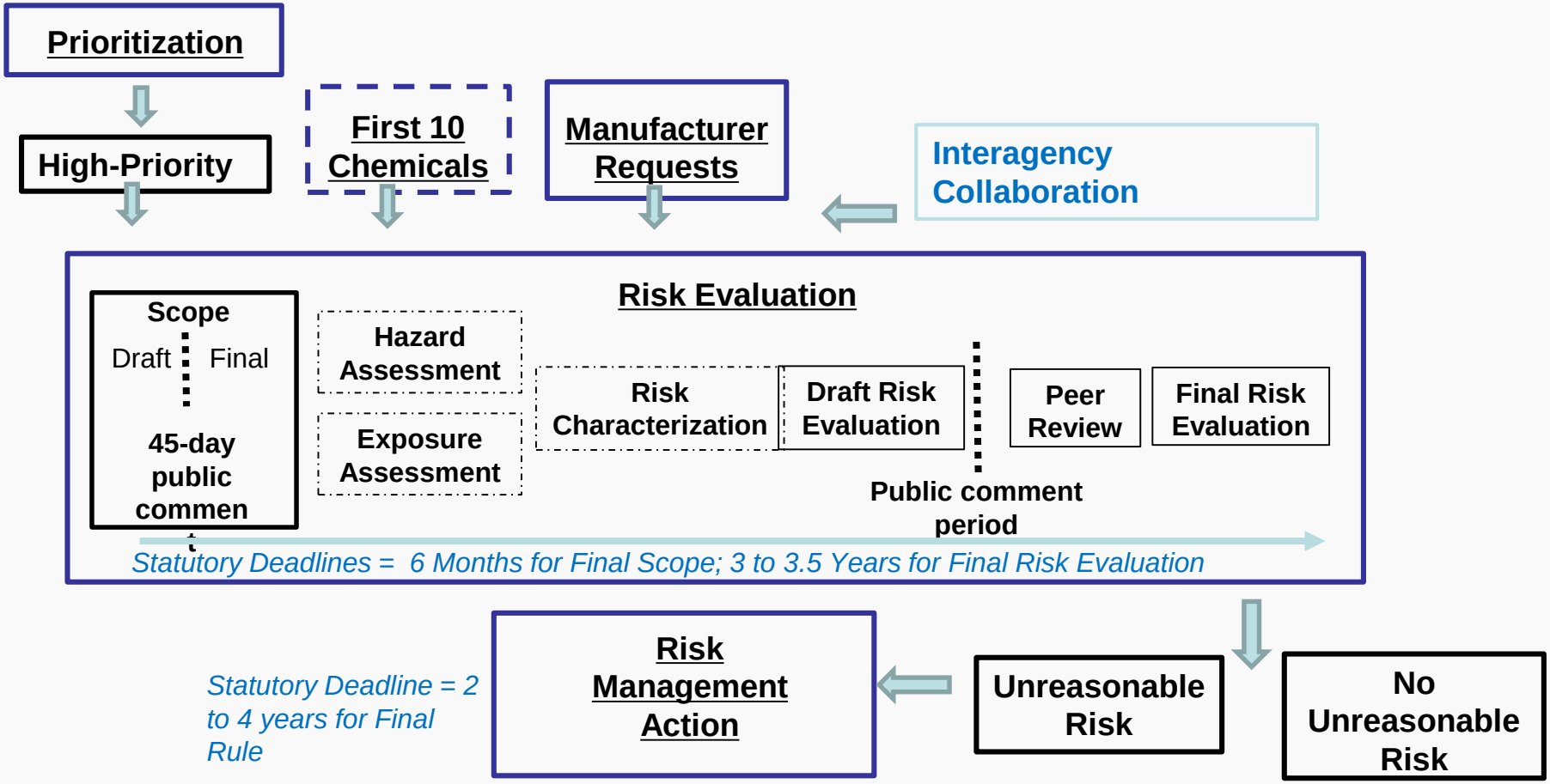
Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for Trichloroethylene (TCE)
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 – 3.5 years

Risk Evaluation Process and Timeline



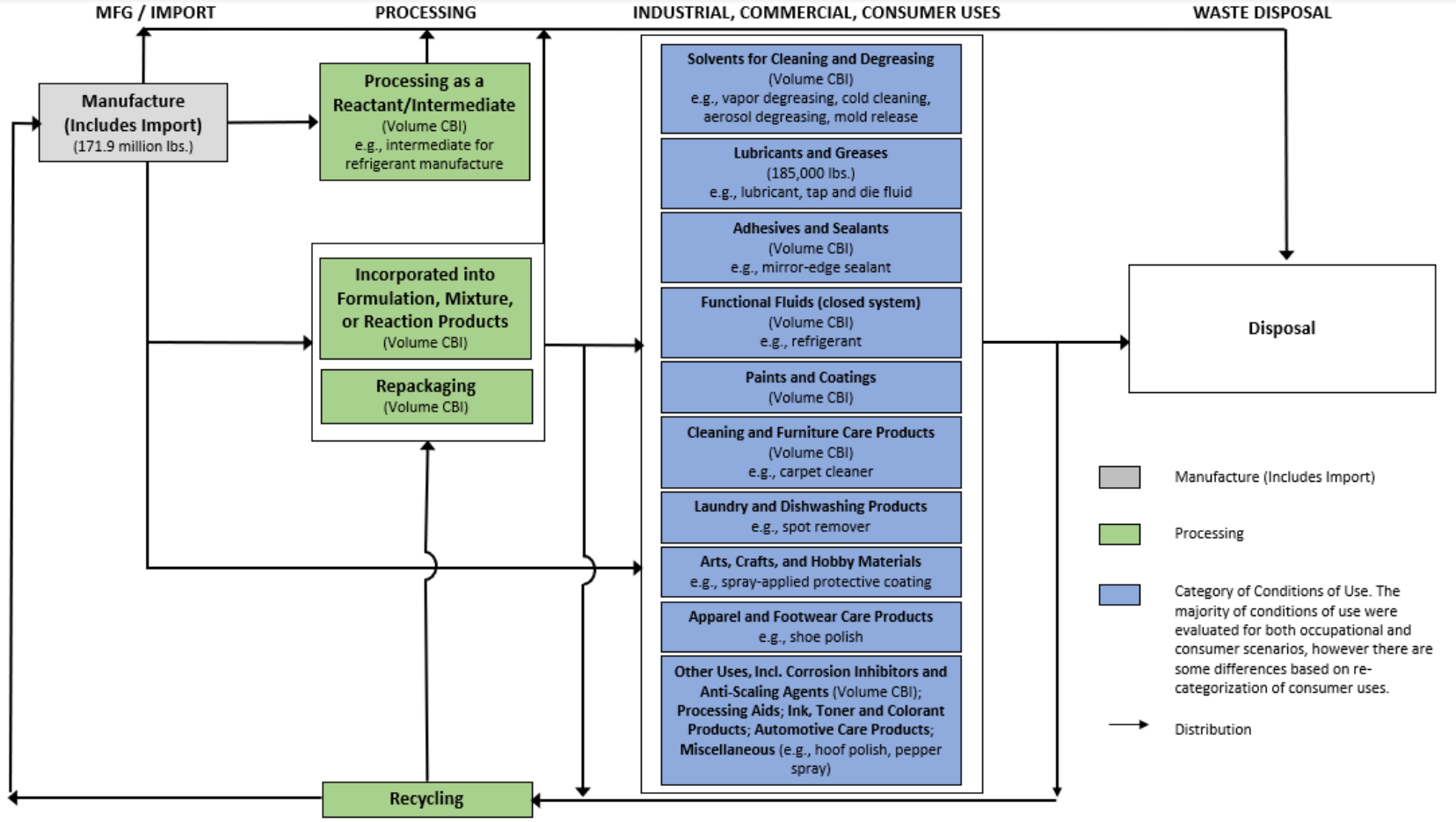
Overview of Risk Evaluation for TCE

- Final risk evaluation published November 25, 2020
  - 54 conditions of use were evaluated
  - Final risk evaluation follows a series of risk evaluation activities
  - Trichloroethylene (TCE) draft risk evaluation: February 2020; TCE problem formulation: June 2018; TCE scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
  - 70 public comments received on the draft risk evaluation (comment period closed April 27, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (March 2020)
- The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0500, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0737, on www.regulations.gov

General Information on TCE

- TCE is a colorless liquid and a volatile organic compound (VOC) with a pleasant, sweet odor resembling chloroform. It is both produced in and imported into the United States
- EPA identified conditions of use during various life cycle stages of TCE, such as manufacturing (including import), processing, distribution in commerce, use (industrial, commercial, and consumer), and disposal
- TCE has a wide range of uses, including as a solvent in vapor degreasing, as a processing aid, or in paints and coatings
- A variety of consumer and commercial products use TCE as a solvent including adhesives and sealants, paint and coatings, automotive care products, and cleaning and furniture care products
- The total aggregate production volume decreased from 220.5 to 171.91 million pounds between 2012 and 2015

TCE Life Cycle Diagram



Determinations of No Unreasonable Risk

- EPA determined that TCE does not present an unreasonable risk to the environment under the conditions of use
- EPA determined that the following two of the 54 conditions of use of TCE do not present an unreasonable risk of injury to health or the environment:
  - Distribution in commerce
  - Consumer use in pepper spray
- These no unreasonable risk determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)

Unreasonable Risk Determinations

- EPA determined that 52 of the 54 conditions of use of TCE present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
  - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for non-cancer adverse effects from acute inhalation and dermal exposures (immunosuppression effects), non-cancer adverse effects from chronic inhalation and dermal exposures (autoimmunity effects), and cancer from chronic inhalation and dermal exposures to TCE

Manufacturing, Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Domestic manufacture
- Import
- Processing: processing as a reactant/intermediate
- Processing: incorporation into a formulation, mixture, or reaction product
- Processing: incorporation into articles
- Processing: repackaging
- Processing: Recycling
- Industrial and commercial use as a solvent for open-top batch vapor degreasing
- Industrial and commercial use as a solvent for closed-loop batch vapor degreasing
- Industrial and commercial use as a solvent for in-line conveyorized vapor degreasing
- Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing
- Industrial and commercial use as a solvent for cold cleaning
- Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release
- Industrial and commercial use as a lubricant and grease in tap and die fluid
- Industrial and commercial use as a lubricant and grease in penetrating lubricant
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant

Industrial and Commercial Uses and Disposal that Present an Unreasonable Risk

- Industrial and commercial use as a functional fluid in heat exchange fluid
- Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coatings
- Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
- Industrial and commercial use in laundry and dishwashing products in spot remover
- Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings
- Industrial and commercial use in corrosion inhibitors and anti-scaling agents.
- Industrial and commercial use as processing aids in process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture
- Industrial and commercial use as ink, toner and colorant products in toner aid
- Industrial and commercial use in automotive care products in brake parts cleaner
- Industrial and commercial use in apparel and footwear care products in shoe polish
- Industrial and commercial use in hoof polish; gun scrubber; pepper spray; other miscellaneous industrial and commercial uses
- Disposal

Consumer Uses that Present an Unreasonable Risk

- Consumer use as a solvent in brake and parts cleaner
- Consumer use as a solvent in aerosol electronic degreaser/cleaner
- Consumer use as a solvent in liquid electronic degreaser/cleaner
- Consumer use as a solvent in aerosol spray degreaser/cleaner
- Consumer use as a solvent in liquid degreaser/cleaner
- Consumer use as a solvent in aerosol gun scrubber
- Consumer use as a solvent in liquid gun scrubber
- Consumer use as a solvent in mold release
- Consumer use as a solvent in aerosol tire cleaner
- Consumer use as a solvent in liquid tire cleaner
- Consumer use as a lubricant and grease in tap and die fluid
- Consumer use as a lubricant and grease in penetrating lubricant
- Consumer use as an adhesive and sealant in solvent-based adhesive and sealant

Consumer Uses that Present an Unreasonable Risk cont.

- Consumer use as an adhesive and sealant in mirror edge sealant
- Consumer use as an adhesive and sealant in tire repair cement/sealer
- Consumer use as a cleaning and furniture care product in carpet cleaner
- Consumer use as a cleaning and furniture care product in aerosol spot remover
- Consumer use as a cleaning and furniture care product in liquid spot remover
- Consumer use in arts, crafts, and hobby materials in fixative and finishing spray coatings
- Consumer use in apparel and footwear products in shoe polish
- Consumer use in fabric spray
- Consumer use in film cleaner
- Consumer use in hoof polish
- Consumer use in toner aid

Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of TCE:
  - Immunosuppression effects from acute inhalation and dermal exposures
  - Autoimmunity effects from chronic inhalation and dermal exposures
  - Cancer effects (kidney) from chronic inhalation and dermal exposures
- Personal Protective Equipment (PPE):
  - The OSHA Trichloroethylene Standard sets a permissible exposure limit (PEL) of 100 ppm as an 8-hr time-weighted average and suggests air supplied respirators for occupational use.
  - Many conditions of use presented an unreasonable risk to workers even with use of respirators APF 25 or 50 and gloves with PF 10 or 20
  - EPA does not assume that it is a standard industry practice that workers in some small commercial facilities (*e.g.,* those performing spot cleaning, wipe cleaning, shoe polishing, hoof polishing, or commercial printing and copying) have a respiratory protection program or regularly employ dermal protection. Therefore, the use of respirators and gloves is unlikely for workers in these facilities.
  - EPA does not assume ONUs use PPE because they do not handle the chemical

Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures of TCE:
  - Immunosuppression effects from acute inhalation and dermal exposure
- EPA does not assume dermal exposure to TCE for bystanders
- EPA does not assume consumers or bystanders use PPE
- The unreasonable risk determinations were based on the high intensity risk estimates for consumers and bystanders. Unreasonable risk was also presented for moderate intensity risk estimates for many COUs
- EPA did not evaluate chronic exposures to TCE for consumer users and bystanders because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing, and distribution level in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

Examples of Regulatory Options

- Set a concentration for a particular use, for example, product formulations cannot contain more than a certain percentage by weight
- Provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describes the health endpoints
- Prohibit manufacturing, processing and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls, ventilation requirements, and PPE at occupational sites
- Require manufacturers, processors, and distributors to maintain ordinary business records

Examples of Regulatory Options

- Require manufacturers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL)
- Require a hazard communication program to educate workers on label directions, warnings, etc.
- Prohibit or regulate manner of commercial disposal
- Restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification

TSCA Section 6(c)

In promulgating any rule under 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health,
- The effects and magnitude of exposure to environment,
- The benefits of the chemical for various uses,
- The reasonably ascertainable economic consequences of the rule, including consideration of:
  - The likely effect on the national economy, small business, technological innovation, the environment, and public health;
  - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives; and
  - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives.

Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs

Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent

Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective

Coordination and Engagement

- In developing risk management approaches EPA:
  - Consults with stakeholders to learn about condition of use, existing engineering controls, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
  - Conducts site visits to obtain detailed information on existing practices in chemical manufacturing, processing, and use
  - Develops an extensive network among all stakeholders to ensure regulatory approaches are fully informed and based on current conditions

Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
- Consultations seeking targeted feedback, with:
  - States and local governments
  - Tribes
  - Small businesses
  - Environmental justice organizations and communities

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- TCE Risk Management: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce
- TCE: Katie McNamara (McNamara.Katelan@epa.gov, 202-564-4361)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)