# Recent TSCA Section 4 Test Orders for High Priority Chemicals

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**Greg Clark**
Partner

Washington, D.C.
202.434.4302
clarkg@khlaw.com

**Javaneh Nekoomaram**
Associate

Washington, D.C.
202.434.4176
nekoomaram@khlaw.com

# Greg Clark

clarkg@khlaw.com • 202.434.4302

Greg Clark is a regulatory and environmental attorney with a focus on the Toxic Substances Control Act (TSCA), the Clean Air Act (CAA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), and state volatile organic compound (VOC) regulations. Additionally, Mr. Clark designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy" and other penalty mitigation policies. Mr. Clark has extensive experience representing clients in CAA rulemakings and enforcement matters before administrative agencies including drafting highly technical comments, filing petitions for reconsideration and judicial review, and meeting with agency staff.

# Javaneh Nekoomaram

nekoomaram@khlaw.com • 202.434.4176

Javaneh Nekoomaram practices environmental, occupational health and safety, and administrative law. She primarily advises clients on Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Occupational Safety and Health Act (OSH Act), and Proposition 65 compliance and represents clients in agency enforcement actions. Javaneh also assists clients in performing internal environmental health and safety audits, advises clients on employment law matters, and participates in appellate level litigation in cases challenging agency rulemakings.

Prior to joining Keller and Heckman, Javaneh served for three years as Counsel for the American Coatings Association where she performed in-house regulatory and government affairs services in areas including TSCA, OSHA, environmental management, product stewardship, and state level chemical policies.

# Agenda

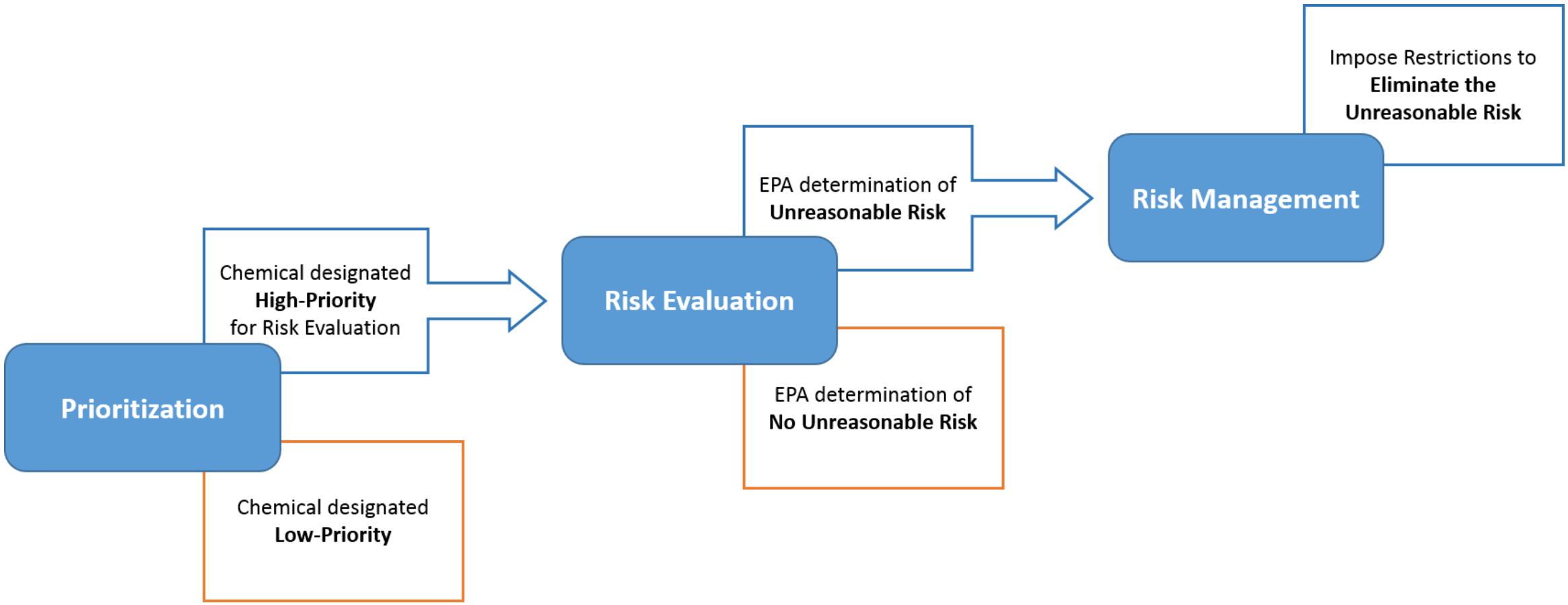
- Introduction
- Background on EPA section 4 authority
- Substances subject to recent test orders
- EPA's reasoning for the orders
- Tests required by the order
- Options to respond
- Timeline for responses
- Use of the data in risk evaluations
- Future considerations

# EPA Section 4 Authority

- 15 U.S.C. §2603
- EPA has authority under TSCA to require testing of substance or mixture by rule, order, or consent agreement
- EPA can require testing to develop information for:
  - Pre-manufacture notifications
  - Risk evaluations under TSCA Section 6(b)
  - To implement a requirement imposed in a rule, order, or consent agreement under TSCA Section 5(e) or (f), or a rule under 6(a)
  - Upon request of a federal authority under another federal law
  - Prioritization
  - To determine if export-only substance presents unreasonable risk

# High Priority Substances Subject to Recent Test Orders

1. 1,1,2-Trichloroethane
2. 1,1-Dichloroethane
3. 1,2-Dichloroethane
4. 1,2-Dichloropropane
5. 4,4’-(1-Methylethylidene)bis[2,6-dibromophenol]
6. o-Dichlorobenzene
7. p-Dichlorobenzene
8. Phosphoric acid, Triphenyl Ester
9. trans-1,2-Dichloroethylene




Source: EPA https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca

# EPA's Reasoning for Test Orders

- EPA issued orders under TSCA Section 4 authority
- Will inform EPA for purposes of risk evaluations under TSCA Section 6(b)
- EPA authorized to require the development of health and safety information and exposure information on substances and to control unreasonable risks
- EPA requiring development of information and the use of prescribed protocols and methodologies
- EPA identified information needs based on final scoping document

| | |
|---|---|
| **Environmental hazard** | |
| Sediment-Water Chironomid life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment | OECD 233 (2010) |
| Spiked Whole Sediment 10-Day Toxicity Test, Freshwater Invertebrates | OPPTS 850.1735 |
| Aquatic Plant Toxicity Test Using Lemna spp. | OCSPP 850.4400 (2012) |
| Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment | OECD 225 (2007) |
| Algal Toxicity | OCSPP 850.4500 (2012) |
| Earthworm Reproduction Test (Eisenia fetida/Eisenia Andrei) | OECD 22 (20216) |
| **Exposure** | |
| Occupational Inhalation Exposure at each facility under your company's control where there is potential for exposure to [SUBSTANCE] | NIOSH Method 1003 (2003) |
| Dermal Hand Wipe Sampling-Solvents at each facility under your company's control where there is potential for exposure to [SUBSTANCE] | Enclosure F of order |
| Dermal Absorption: In Vitro Method using human and animal skins | OECD 428, (2004) |
| Inhalation Sample protocol for flame retardants; dermal hand wipe sample for flame retardants | Enclosure G of order |

# Options for Responding to Test Order

1. Develop the requested information
2. Submit existing information
3. Request an exemption
4. Claim not a manufacturer or processor
5. Cease manufacture and/or processing

# Options for Responding (cont'd)

## 1. Develop the requested information

- Perform the tests requested by EPA
- Negotiate study plan with EPA
- Cost reimbursement from companies that request and receive exemptions from testing
- Indicate if joining a testing consortium

# Options for Responding (cont'd)

## 2.Submit existing information

- Information must be submitted with Initial Response
- Indicate if joining a consortium
- EPA may reject 10 days to choose another option
- Other deadlines are pushed back by number of days EPA took to respond

# Options for Responding (cont'd)

## 3.Request an exemption

- EPA wants to avoid duplicative information
- Dependent on other company(ies) submitting information
- May be on an "equivalent chemical" under a section 4 rule, order, or consent agreement
- Obligation to reimburse company(ies) that test
  - Negotiated reimbursement or by EPA order

# Options for Responding (cont'd)

## 4. Claim not a manufacturer or processor

- Include supporting information to substantiate the claim
- Original deadlines apply if EPA rejects claim
- EPA intended to exclude processing reported under TRI category "As an Impurity"

# Options for Responding (cont'd)

## 5. Cease manufacture and/or processing

- Cease manufacture or processing, as appropriate, within 90 days of the effective date of the order
- Submit a certification from an authorized representative of the company
- Possible to resume, but will require a new response to the order

# Approximate Timeline for Responses

- Initial Response with choice (and consortium): 45 days → March 5
- Notify EPA of fees consortium: 60 days* → March 15
- Submit initial study plans: 75 days → April 4
- Test order fee: 120 days → May 19
- Submit final study plans: 60 days* → June 3
- Submit final reports for occupational exposure, ecotoxicity, dermal absorption studies → 8, 9, 12, or 13 months

*Timing not calculated from January 19 effective date

# Use of the Data in Risk Evaluations

- Filling data gaps
- EPA likely to use highest exposure and most sensitive organism
- Final risk evaluations due December 2022 (or June 2023, if extended)
  - Draft risk evaluations ~December 2021
- Unclear impact of EPA changes to TSCA systematic data review that was faulted by National Academy of Sciences

# Future Considerations

- Test orders "allow EPA to target known manufacturer and processor recipients to obtain the needed information more quickly" than test rules or consent agreements
- Submit existing data early, or negotiate a timeline with EPA
  - *e.g.*, industrial hygiene data
- Negotiate use of data submitted for other regimes
  - *e.g.*, REACH
- Identify acceptable chemical analogues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March 17, 2021
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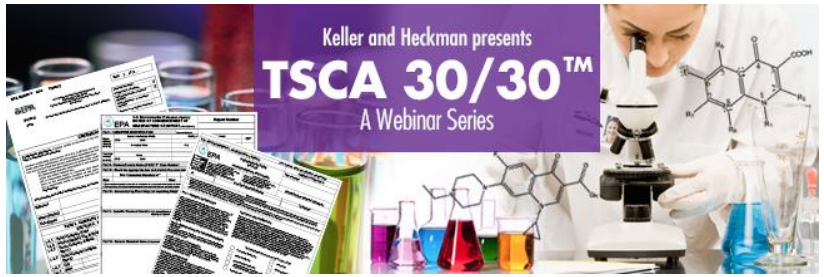


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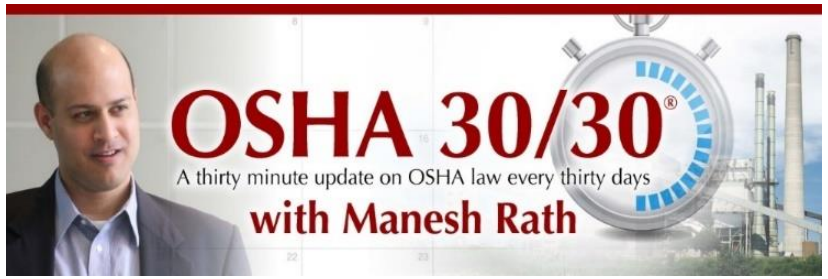


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# Thank You!

**Greg Clark – clarkg@khlaw.com; 202.434.4302**
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