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05/23/2022	Petition for Review	2	PETITION FOR REVIEW [1947770] of a decision by federal agency filed by Vinyl Institute, Inc. [Service Date: 05/23/2022] Disclosure Statement: Attached. [22−1089]
06/23/2022	Underlying Decision in Case Filed	39	UNDERLYING DECISION IN CASE [1951763] submitted by Vinyl Institute, Inc. [Service Date: 06/23/2022] [22−1089] (Gotting, Eric)
08/26/2022	Motion Filed	72	MOTION [1961119] to supplement record filed by Vinyl Institute, Inc. (Service Date: 08/26/2022 by CM/ECF NDA) Length Certification: 5163 words. [22−1089] (Gotting, Eric)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

VINYL INSTITUTE, INC., Petitioner, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	22-1089

PETITION FOR REVIEW

Pursuant to 15 U.S.C. § 2618 of the Toxic Substances Control Act ("TSCA"), Fed. R. App. P. 15(a), and Circuit Rule 15(a), Petitioner Vinyl Institute, Inc. ("VI"), hereby petitions the Court for review of the United States Environmental Protection Agency's ("EPA") *Order Under Section 4(a)(2) of the Toxic Substances Control Act* ("Test Order"), issued on March 24, 2022, and with an effective date of March 29, 2022. The Test Order is attached hereto as **Exhibit A**. This Court has jurisdiction and is the proper venue for these proceedings pursuant to 15 U.S.C. § 2618(a)(1)(A).

The Test Order requires designated companies to develop certain information regarding 1,1,2-trichloroethane that EPA maintains is necessary to perform a risk evaluation under TSCA Section 6(b) (*see* 15 U.S.C. § 2605(b)). VI

member companies are among those companies required by the Test Order to develop information, and the VI manages a consortium that will respond to the Test Order.

The VI seeks judicial review of the Test Order under federal law, including but not limited to the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* ("APA"), the Toxic Substances Control Act, 15 U.S.C. § 2601, *et seq.*, and EPA's regulations promulgated thereunder.

The VI seeks a determination by this Court that, *inter alia*, the Test Rule: (i) violates the above-referenced authorities; (ii) is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law; (iii) is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (iv) is without observance of procedure required by law; (v) is unsupported by substantial evidence (*see* 15 U.S.C. § 2618(c)); and (vi) is otherwise contrary to law.

Accordingly, the VI respectfully requests that this Court hold unlawful, vacate, enjoin, set aside, and remand the Test Order, and grant such other relief as the Court may deem appropriate.

Respectfully submitted,

/s/ Eric P. Gotting

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Counsel for Vinyl Institute, Inc.

Dated: May 23, 2022

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1, Petitioner Vinyl Institute, Inc. ("VI") submits this corporate disclosure statement. The VI is a trade association representing the interests of the leading manufacturers of vinyl, vinyl chloride monomer, vinyl additives and modifiers, and vinyl packaging materials. It is incorporated under the not-for-profit corporation laws of the District of Columbia. The VI has no parent companies and has not issued any shares or debt securities to the public.

Dated: May 23, 2022

/s/ Eric P. Gotting

CERTIFICATE OF SERVICE

I hereby certify that, on May 23, 2022, I sent file-stamped copies of the forgoing Petition for Review to the following parties by the manner indicated:

By Certified Mail, Return Receipt Requested
The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Ave., N.W.
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Washington, D.C. 20004

By Certified Mail, Return Receipt Requested
Jeffrey Prieto, Esq.
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Washington, D.C. 20460

By Certified Mail, Return Receipt Requested
Correspondence Control Unit
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U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
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Washington, D.C. 20460

By Certified Mail, Return Receipt Requested
Merrick B. Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington DC 20530-0001

Pursuant to 15 U.S.C. § 2618(a)(2), the Clerk of Court is respectfully requested to transmit this Petition for Review to the EPA Administrator and the Attorney General of the United States.

Dated: May 23, 2022

/s/ Eric P. Gotting

EXHIBIT A

U.S. Environmental Protection Agency, *Order Under Section 4(a)(2) of the Toxic Substances Control Act* (March 24, 2022)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 24, 2022

Order Under Section 4(a)(2) of the Toxic Substances Control Act

Chemical Substance Subject to this Order:

Chemical Name: 1,1,2-Trichloroethane

Chemical Abstracts Service Registry Number (CASRN): 79-00-5

Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0421[1]

Testing Required by this Order:

1. Environmental Hazard
    - Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
    - Avian Reproduction Test

Recipients of this Order:

Company Name: C-K TECH INC

Company Name: KEM KREST LLC

Company Name: FORMOSA PLASTICS CORP USA

Company Name: HAAS GROUP INTERNATIONAL

Company Name: OCCIDENTAL CHEMICAL HOLDING CORP

Company Name: OLIN CORP

Company Name: WESTLAKE CHEMICAL CORP

Dear Recipient:

This Order requires you and the other named manufacturer(s) and/or processor(s) of 1,1,2-trichloroethane (CASRN 79-00-5) to develop and submit certain information for 1,1,2-trichloroethane, or otherwise respond to the U.S. Environmental Protection Agency (referred to herein as "the EPA" or "the Agency"). Failure to respond to this Order, or failure to otherwise comply with its requirements, is a violation of section 15 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2614. Any person

[1] To access the docket, go to https://www.regulations.gov.

who violates TSCA shall be liable to the United States for penalties in accordance with TSCA section 16, 15 U.S.C. § 2615.

This Order is **effective 5 calendar days after its date of signature by the EPA**. The timeframes and options for responding are described in **Unit IV** (Response Options). Please note that the email transmitting this Order to you will provide the calendar date for the response deadlines as defined in **Unit III** (Deadlines for Responding to this Order). A subsequent email will provide a company specific Order number for you to use in responses and communications about this Order.

This Order is organized as follows:

I. PURPOSE AND AUTHORITY

A. OVERVIEW

This Order is being issued under the authority of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. TSCA section 4 authorizes the EPA to require the development of necessary information related to chemical substances and mixtures.

This Order requires the identified recipients to develop and submit new information on 1,1,2-trichloroethane (CASRN 79-00-5) that is necessary for the EPA to perform a risk evaluation under TSCA section 6(b).

Information on testing requirements is provided in **Appendix E**. The EPA encourages the formation of industry consortia to jointly conduct testing between the recipients of this Order. See **Unit VIII** for more information on this topic.

The Order provides four response options, listed below. More information on each of these options is provided in **Unit IV**. Timeframes for these options is provided in **Unit III**. Note that the deadline to identify as a manufacturer, processor, or both is 30 calendar days of the effective date of this Order. This step is necessary for purposes of this Order to ensure that your company can appropriately access the CDX application used for responding to section 4 orders.

Option 1: Develop the Information
Use this option to develop information in response to all of the requirements of this Order that apply to you, or use this option in conjunction with other response options identified in this section as appropriate.

Manufacturers who are required to test a chemical substance or mixture pursuant to a TSCA section 4 order are also required to pay a fee (see **Unit VII**).

Option 2: Submit Existing Information
Use this option to submit an existing study and/or other scientifically relevant information that you believe the EPA has not considered, along with supporting rationale that explains how the submittal(s) meets part or all of the information described as necessary in **Unit II**. If the Agency determines that the submitted information satisfies one or more data needs identified by this Order, the Agency will extinguish any associated test requirement(s).

Option 3: Request an Exemption
Use this option to request an exemption from a testing requirement of this Order. The EPA will grant an exemption if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement; and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

Option 4: Claim that You Are Not Subject to this Order
Use this option to claim that you are not subject to this Order. You may claim that you are not subject to this Order if all of the following are true:

1. You do not currently manufacture or process the chemical(s) identified by this Order;

2. You do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order; and

3. You have not manufactured or processed the chemical(s) at any time during the five years preceding the date of this Order.

You must provide an explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim.

B. Terminology Used in this Order

The term "manufacture" means to import into the customs territory of the United States, to produce, or to manufacture. 15 U.S.C. § 2602(9). Import also includes importing the chemical as an impurity in an article.

The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture. 15 U.S.C. § 2602(13).

The term "chemical" or "substance" means a chemical substance or mixture.

C. Persons Subject to this Order

1. Persons Identified

An order issued under section 4(a) of TSCA may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the order. The recipients of this Order are listed at the top of the Order.

For purposes of this Order, a recipient identified by this Order is subject to the Order if it has manufactured or processed the chemical at any time during the five years preceding the date of this Order. If a recipient identified by this Order has not manufactured or processed the chemical during the prior five years, the recipient is nevertheless subject to the Order if they intend to manufacture or process the chemical within the period of testing provided by this Order.

A person who contracts with a producing manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the producing manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

A recipient who is an importer of record of a chemical substance identified by this Order is responsible for the testing requirements of this Order, even if the recipient does not store, handle, use, or otherwise directly deal with the chemical.

The means by which the EPA identified each recipient subject to this Order does not govern whether a recipient is subject to this Order. Ultimately, any recipient that meets the criteria discussed in this section is subject to this Order, regardless of the basis on which the Agency identified the recipient.

2. Corporate Structure of Recipients: Changes of Ownership

The EPA has attempted to identify the highest-level U.S. corporate entity for purposes of issuing this Order. The highest-level U.S. corporate entity is ultimately responsible for satisfying the obligations of this Order, although the highest-level U.S. corporate entity may delegate its responsibilities under this Order to a U.S. subsidiary. Where the corporate entity named in this Order is not the highest-level U.S. corporate entity, the Agency nonetheless considers notification of the company named in this Order to

constitute notification of the highest-level U.S. corporate entity and holds the highest-level U.S. corporate entity ultimately responsible for satisfying the obligations of this Order.

Should you wish to modify the name of the recipient or identify another U.S. corporate entity in the corporate structure as the point of contact in place of the recipient named in this Order, you must submit a request to the EPA. Submit your request, justification for the change, and contact information for the representatives of the newly named entity to TSCAtestorders@epa.gov. A representative from the Agency will contact you and any other representatives regarding this request.

In the event of mergers, acquisitions, or other transactions that create a corporate successor in interest (subsequent to the manufacturing or processing that triggered the reporting obligation, and either before or after receipt of this Order), that successor in interest is responsible for satisfying the obligations of this Order. The successor in interest must notify the EPA of its identity within 14 days following the transaction.

D. Previously Issued Orders

The EPA previously issued a test order for 1,1,2-trichloroethane, effective January 19, 2021, to meet other data needs. See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane[2].

Since issuing that test order, the EPA's continuing review of the reasonably available information has identified additional information needed to inform the associated risk evaluation. Accordingly, the Agency is issuing this additional Order for 1,1,2-trichloroethane. See the Statement of Need for further details. This Order does not alter the requirements of any previous test orders.

II. STATEMENT OF NEED

The basis for requiring the development of new information by this Order is described in this unit and in **Appendix E**. This statement of need, as required by TSCA section 4(a)(3), includes: (A) the need for the new information; (B) how information reasonably available to the Administrator was used to inform the decision to require the new information; (C) why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement; and (D) (if applicable) the basis for the Agency's decision to require testing of vertebrate animals. **Appendix E** (Testing Requirements of This Order) indicates which tests apply specifically to manufacturers and/or processors subject to this Order.

A. The Need for the New Information

This section and **Appendix E** explain what new information is being required in this Order and why such information is needed for the risk evaluation of 1,1,2-trichloroethane under TSCA section 6(b).

The EPA has identified the following information in this section as necessary to conduct a risk evaluation to determine whether 1,1,2-trichloroethane presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use (COU).

[2] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane*

The next unit will outline how the EPA came to determine these new information needs. Note that additional details for these testing requirements are provided in **Unit V** and **Appendix E**.

1. Environmental Hazard

Information on hazards to aquatic and terrestrial organisms is needed to conduct a risk evaluation. The relevant environmental hazard data needs that this Order seeks to address for 1,1,2-trichloroethane, as described below, are as follows:

- Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
- Avian Reproduction Test

B. How Information Reasonably Available to the Administrator Was Used to Inform The Decision to Require New Information

This section details the "Scoping and Conceptual Models" and "Systematic Review of Reasonably Available Existing Information" processes used by the EPA to identify, respectively, what information is reasonably available to integrate into the risk evaluation for the conditions of use of 1,1,2-trichloroethane and ascertain, via a "Discipline-Specific Approach for Identifying Data Needs" what needed information is not reasonably available in existing literature (i.e., what testing to require).

1. Scoping and Conceptual Models

The *Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane* (https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf[3]) (hereinafter "*Final Scope*") includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane. The Agency has used the scope document and the conceptual models therein for workers and occupational non-users (ONUs), consumers and bystanders, general population, and environmental releases as a starting point for identifying information needs under this Order. The conceptual models visually represent the human and environmental exposures (pathways and routes), receptors, and hazards associated with the conditions of use of 1,1,2-trichloroethane. For each exposure (pathway and route), receptor, and hazard that is visually represented, the EPA has identified the information needed to conduct a risk evaluation for this chemical.

In addition, since publication of the *Final Scope*, the EPA has reconsidered the policy decision to exclude from the scope of TSCA section 6(b) risk evaluations certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. Based on that reconsideration, the Agency now also intends to consider in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane all of the exposure pathways portrayed in Figure 2-15 (Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)) of the *Final Scope*, and has identified the information needed for that assessment.

2. Systematic Review of Reasonably Available Existing Information

The systematic review process began with searching peer-reviewed literature databases (*e.g.*, Agricola, PubMed, Science Direct, ECOTOX Knowledgebase) for studies using 1,1,2-trichloroethane, synonyms,

[3] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf*

and trade names. The EPA also conducted a search of gray literature (*e.g.*, technical reports, reference books, dissertations, and other information not found in standard, peer-reviewed literature databases), as well as review of public comments posted to the docket for this chemical substance during the prioritization process and following publication of the draft scope document, relevant data and information submitted to the Agency under TSCA sections 4, 5, 8(e), 8(d), and For Your Information (FYI) submissions. The collected compilation of information was then screened for relevance. This process applied title/abstract screening and/or full-text screening based on screening criteria developed *a priori* for environmental hazard and consumer exposure (Population, Exposure, Comparator and Outcomes (PECO)); physical and chemical properties (Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO)) or occupational exposure literature (Receptors, Exposure, Setting or Scenario, and Outcomes (RESO)).

3. Discipline-Specific Approach for Identifying Data Needs

a. Environmental Hazard

The EPA defined the pathways and routes of exposure, receptors, and hazards for environmental releases and wastes that are expected to be evaluated in the *Final Scope* (Figure 2-15 pg. 44). As noted above, since publication of the *Final Scope*, the Agency has reconsidered the policy decision to exclude from the scope of TSCA section 6(b) risk evaluations certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. The Agency intends to consider all aquatic and terrestrial exposure pathways in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane, and has identified the information needed for that assessment.

As determined in the *Final Scope*, the manufacturing, processing, distribution, use and disposal of 1,1,2-trichloroethane can result in releases to the environment and exposure to aquatic and terrestrial organisms. The EPA expects to assess environmental hazards and risks to both aquatic and terrestrial plants, invertebrates, and vertebrates and therefore requires hazard data for each of these assessment endpoints. The Agency also expects to assess organisms for both aquatic and terrestrial hazard when those organisms transition between aquatic and terrestrial ecosystems depending on the life stage evaluated (e.g., midges inhabit sediment as larvae but mature into adults that inhabit terrestrial and aquatic ecosystems).

Identification of the reasonably available information for 1,1,2-trichloroethane included consideration of existing data for the parent chemical and analogous chemicals for aquatic and terrestrial exposure pathways. The EPA identified seven analogues to 1,1,2-trichloroethane using EPA's Analog Identification Methodology (AIM) software (see **Unit II.B, Environmental Hazard – Analogues Table**). The Agency identified existing measured environmental hazard data for aquatic and terrestrial species for 1,1,2-trichloroethane and the identified analogues from the EPA's ECOTOX Knowledgebase (ECOTOX) and information submitted under TSCA, (e.g., under Sections 4 and 8e), FIFRA, and the Endocrine Disruptor Screening Program (EDSP).

Pursuant to this Order, the EPA is requiring data be submitted to facilitate evaluation of risk to terrestrial organisms. An order requesting testing to fill the aquatic data gaps identified for 1,1,2-trichloroethane was issued previously (see **Unit XI, References**). As shown in the table below, terrestrial environmental hazard data were identified for 1,1,2-trichloroethane and two of the seven identified analogues. These data covered exposures of 1,1,2-trichloroethane to terrestrial vegetation, acute exposures to soil invertebrates, mammals, and birds, and chronic exposures to mammals. No toxicity data for chronic exposures to soil invertebrates or birds were identified.

Table 1. Terrestrial Environmental Hazard – Analogues

Chemical Name	CASRN	Environmental Hazard Data Availability for 1,1,2-Trichloroethane						
		Acute Exposure			Chronic Exposure			Vegetation
		Soil Invertebrate	Mammal	Bird	Soil Invertebrate	Mammal	Bird	
1,1,2-Trichloroethane	79-00-5	X	X	X	-	X	-	X
Analogues for 1,1,2-Trichloroethane								
1,1,1-Trichloroethane	791-55-6	X	X	X	-	-	-	X
Trichloroethane	25323-89-1	-	-	-	-	-	-	-
1,2,3-Trichloropropane	96-18-4	-	X	-	-	-	-	-
1,2,3,4-Tetrachlorobuta-1,3-Diene	1637-31-6	-	-	-	-	-	-	-
1,1,5,5-Tetrachloropentane	17655-64-0	-	-	-	-	-	-	-
1,1,2,3-Tetrachloropropane	18495-30-2	-	-	-	-	-	-	-
1,2,3,4-Tetrachlorobutane	3405-32-1	-	-	-	-	-	-	-

X signifies data were identified and "-" signifies a gap, where no data were identified

C. Why Issuance of this Order is Warranted Instead of Promulgating a Rule or Entering Into a Consent Agreement

The EPA is using its order authority under TSCA section 4(a)(2) to inform the risk evaluation for 1,1,2-trichloroethane under TSCA section 6(b) in accordance with the requirements and timeframes for conducting the risk evaluation. Use of this TSCA section 4(a)(2) authority will allow the Agency to target known manufacturer and processor recipients to obtain the needed information more quickly than if the EPA were to issue a TSCA section 4 rulemaking or consent agreement.

D. The EPA Determined that Vertebrate Testing is Needed in this Order

The EPA has determined that vertebrate testing is needed to assess the particular exposure pathways and receptors discussed in this Order. Reasonably available data, computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing required by this Order (see below for details). The analysis for determining data needs described in **Unit II.B** included use of acceptable new approach methodologies (NAMs), specifically the EPA computational toxicology and informatics tools such as AIM, to identify analogues with existing information that could potentially fill data needs. A list of the testing on vertebrates required by this Order as well as further information on the EPA review process that led to the inclusion of such testing requirements can be found in **Unit II.B** and **Appendix E**, as well as below.

1. Environmental Hazard: Avian Reproduction Test

No avian toxicity data following chronic exposures were identified for 1,1,2-trichlorethane or identified analogues for any endpoints. No approved or readily available new approach methodologies (NAMS) were identified that could be used to inform the data gap for avian toxicity following chronic exposure. Without toxicity data, the EPA is unable to determine if chronic exposures to 1,1,2-trichlorethane pose a risk to terrestrial vertebrates. Office of Pesticide Programs recently released a guidance that describes instances where sub-acute dietary testing in birds may be waived (U.S. EPA, 2020). This waiver specifically outlines instances where the

animal testing burden can be reduced by requesting only acute testing oral testing in birds and waiving the traditional requirement for both acute oral testing and sub-acute dietary testing with avian species. As this Test Order does not request acute oral testing with birds nor sub-acute dietary testing with birds, this waiver request is not relevant. The Agency has worked to ensure that the animal testing burden under TSCA is reduced by utilizing all available ecotoxicity data and tailoring data needs to the specific properties of each chemical. The testing requirement is reinforced by avian toxicity data captured in the peer-reviewed literature undergoing systematic review, which qualitatively indicates exposure to 1,1,2-trichloroethane caused developmental toxicity to chick embryos (Elovaara, 1979). While the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure, the evidence of teratogenicity in chick embryos indicates that additional data are needed to understand the potential effect following chronic dietary exposure. Monitoring data from USGS's National Water Quality Monitoring Council has also identified 1,1,2-trichloroethane in media to which terrestrial vertebrates could be exposed, including ground water, sediment, soil, surface water and biota (USGS, 1991).

III. DEADLINES FOR RESPONDING TO THIS ORDER

This section describes the deadlines for this Order and possible modifications to such deadlines.

A. DEADLINES FOR RESPONSES TO THIS ORDER

The table below provides the deadlines for this Order. Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday. Descriptions of these response options and the required process associated with each option is provided in **Unit IV**.

Table 2. Deadlines for Responses, Study Plans, and Test Reports

Order Requirement	Recipient's Deadline (Days after the effective date of the Order)	EPA Response Deadline*
• Identify as a Manufacturer, Processor or Both	30	n/a
• Submit Request to Modify Corporate Identity Identified	30	n/a
• Choose to Submit Existing Data (Option 2)	30	45
• Claim that You Are Not Subject to this Order (Option 4)	45	60
• Choose to Develop the Information - On Own or as Part of a Consortium (Option 1)	65	n/a
• Request an Exemption (Option 3)	65	80
• Submit Draft Study Plan	80	95
• Submit Final Study Plan	110	125
• Submit Final Test Report	Deadline varies per Test Requirement (See **Unit V** and **Appendix E**)	

*See **Unit III.B** for potential automatic extensions associated with the EPA responses. Deadlines for submitting final test reports for each required test are provided in **Appendix E**.

B. AUTOMATIC EXTENSIONS TO DEADLINES

The EPA will automatically extend deadlines should the Agency fail to meet any EPA response deadline set forth in **Unit III.A**. Specifically, deadlines will be automatically extended should the

Agency fail to respond within 15 calendar days of the deadline for a response option if the response was submitted in the CDX application prior to the deadline provided. For each day exceeding the 15-day period following the associated deadline, the EPA will extend subsequent deadlines by one day.

Should a recipient amend their response, at any time, the EPA will not extend any associated or subsequent deadlines. Therefore, the Agency recommends that recipients submit their amendments or extension requests as early as practicable to ensure adequate time to perform any required testing given that the Agency will not automatically extend deadlines for any such amendments to responses.

The EPA will not automatically extend a deadline for a response should the recipient submit its response after the deadline for the given response option. Additionally, the EPA will not automatically extend a deadline for a response should the Agency respond within 15 days of the deadline for a given response option that was submitted on or before the deadline for that response option.

Other than potential automatic extensions to deadlines described here, **Unit III.C** provides the process for requesting an extension to a deadline.

C. Requesting An Extension To A Deadline For Responding To This Order

If you believe you cannot submit the required identification as a manufacturer, processor, or both; Order response; draft study plan; final study plan; or final test report to the EPA by the deadline(s) specified in this Order and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency through the EPA's CDX portal as soon as you know you may need an extension. Your request must include: (1) a detailed description of the expected difficulty, including technical and laboratory difficulties, and (2) a proposed schedule including alternative dates for meeting such requirement(s) on a step-by-step basis.

The EPA will grant or deny deadline extension requests at its discretion.

IV. RESPONDING TO THIS ORDER

You are required to respond to this Order even if you believe your company is not subject to this Order. Failure to provide a response is a violation of section 15 of TSCA.

A. Identify As A Manufacturer, Processor, Or Both

Within 30 calendar days of the effective date of this Order, you, as a recipient of this Order, are required to respond to this Order through the EPA's Central Data Exchange (CDX) portal, informing the Agency whether you will be responding to this Order as manufacturer or processor (if you manufacture and process the chemical, select manufacturer). To provide your preliminary response to this Order, you will receive an e-mail from the EPA within five days of the Order being signed (i.e., by the effective date of the Order) that provides a CDX Order number for purposes of complying with this Order.

You may claim that you are not subject to this Order if you (1) do not currently manufacture or process the chemical(s) identified by this Order; (2) do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and (3) have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order. See **Unit VI.B.4** for more information on how to claim that you are not subject to this Order.

B. Four Response Options

A recipient has four available options for purposes of responding to this Order. See **Unit III** to review the deadlines for this Order.

Option 1: Develop the Information

If you choose to develop information in response to this Order, you must select this option in the CDX portal form.

For details on the steps of this response option, see **Unit VI**.

For more information on this Order's required tests, required protocols/methodologies, and deadlines for submission of test reports see **Unit V** and **Appendix E**.

Option 2: Submit Existing Information

If you choose to respond to this Order by submitting an existing study and/or other scientifically relevant information that you believe the EPA has not considered, your response in the EPA's CDX portal must be submitted to the EPA 30 days after the effective date of the Order and include the study(ies) and/or other scientifically relevant information, along with supporting rationale that explains how the study and/or other scientifically relevant information meets part or all of the information or obviates the need for the information described as necessary in **Unit II**.

The EPA's determination regarding whether the study and/or other relevant information satisfies part or all of the information or obviates the need for the information described as necessary in **Unit II** will be based on the weight of the scientific evidence from all relevant information reasonably available to the Agency. The Agency will notify you of its determination through CDX. If the Agency determines that the study and/or other scientifically relevant information satisfies the need in lieu of the testing required in this Order and/or the original testing requirement is no longer needed, the EPA will extinguish those testing obligations from this Order that are no longer necessary, with respect to the appropriate recipients of this Order. If the study was your only testing obligation under the Order, all your obligations under this Order will be extinguished upon notification by the Agency.

If the EPA determines that the study and/or other scientifically relevant information does not satisfy that need, you must modify your response in the EPA's CDX portal to choose one of the other response options in **Unit IV** within 10 calendar days of being notified by the Agency.

Note that the submission of existing information will not extend the deadline for the draft study plan submission for that testing requirement unless the existing information is submitted within 30 days of the effective date of the Order and the EPA does not respond within 45 days of the effective date of the Order. Thus, failure to submit existing information prior to the 30-day deadline will result in a need to submit a draft study plan by the 80-day deadline. See Unit **III.B** for information on the potential automatic extension of deadlines.

Option 3: Request an Exemption

Any person required by this Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA section 4(c)(1)).

The EPA will grant a request for exemption from the requirement to conduct tests and submit information on a chemical substance if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement, and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

An exemption request must be submitted through the CDX portal and contain the following:

1. This Order number, the chemical identity, and the CAS Registry No. of the test substance subject to this Order on which the application is based.

2. The specific testing requirement(s) from which an exemption is sought.

3. The basis for the exemption request when another company(ies) has/have submitted the information or is/are developing information for the subject chemical or an equivalent chemical pursuant to a TSCA section 4(a) rule, order, or consent agreement. Your request must identify the company(ies) that submitted or is/are developing the information.

4. The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.

5. The equivalence data ("chemical data or biological test data intended to show that two substances or mixtures are equivalent" (see **Appendix A**)), if data on an equivalent chemical is being submitted.

6. The name, mailing address, telephone number, and e-mail address of applicant.

7. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.

8. A Statement of Financial Responsibility: The following sworn statement (i.e., signed and notarized) must accompany each request for an exemption:

> "I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based."

The EPA's grant of an exemption is conditional upon the completion of the required tests according to the specifications of this Order (or other applicable rule, order, or consent agreement), including any modifications approved by the Agency. If the EPA subsequently determines that equivalent data has not been submitted in accordance with the applicable rule, order, or consent agreement, the Agency will provide notice through CDX of its preliminary decision to terminate the exemption. Within 30 days after receipt of such notice, the exemption holder may submit information in the CDX portal either to rebut the EPA's preliminary decision to terminate the exemption or notify the Agency of its intent to develop

the required information pursuant to the specifications established in this Order and any modifications approved by the EPA. If the exemption holder submits information to rebut the EPA's preliminary decision to terminate the exemption, then the Agency will provide the exemption holder an opportunity to request a hearing prior to issuing a final decision to terminate the exemption. Following the receipt of information to rebut the EPA's preliminary decision and any subsequent hearing, the Agency will render a final decision on whether to terminate the exemption, taking into account information submitted to rebut the EPA's preliminary decision and information presented at any hearing, as applicable.

If you receive the EPA's preliminary decision to terminate the exemption and do not submit information to rebut that preliminary decision or request a hearing, or if you receive the Agency's final decision to terminate the exemption following the submission of information to rebut that preliminary decision or a hearing, you must resubmit a response in accordance with one of the options described in **Unit IV.B** of this Order within 30 calendar days of receipt of the EPA's decision to terminate the exemption, including as applicable the information required under **Unit V** of this Order. Failure to timely resubmit the response will constitute a violation of this Order and of TSCA section 15(1). Should the Agency terminate the exemption, a draft study plan will be due 30 days from the termination, with the final study plan being due 60 days from the termination.

If the EPA extinguishes a testing obligation pursuant to **Unit IV.B.2** of this Order, the corresponding exemption will be extinguished, as the exemption will no longer be necessary. In such a situation, companies who requested an exemption from that specific testing obligation are not required to reimburse the company that submitted existing data.

As explained in **Appendix B** on Cost Sharing, persons who receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Normally, this is worked out by the parties involved, without the involvement of the EPA. However, if agreement cannot be reached on the amount or method of reimbursement, and the company who is entitled to reimbursement requests in accordance with the procedures in **Appendix B** that the Agency order reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement. See TSCA section 4(c).

Option 4: Claim that You Are Not Subject to this Order

You may claim that you are not subject to this Order if you do not manufacture or process the chemical(s) identified by this Order; do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order.

An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your response in the CDX portal so that the EPA can evaluate the claim.

Note that if your company ceased manufacturing (including import) or processing of the chemical substance(s) subject to this Order more than five years prior to the effective date of this Order, you can claim that you are not subject to this Order.

In the instance that you claim you are Not Subject to this Order, your claim must include (1) a statement explaining why your company is not subject to this Order, such as no longer importing, manufacturing

or processing the subject chemical substance (intentionally or unintentionally) within the five years prior to the effective date of this Order, and not intending to manufacture (including import) or process the chemical within the period of testing provided by this Order (see **Unit V**), and (2) the certifying statement "I certify that the statements made in this letter are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law."

If based on the evidence you provide and other evidence available to the EPA, the Agency deems your claim to be inadequately substantiated, the EPA will deny your claim, and the original requirements and deadlines in this Order will remain. If your claim is approved, the Agency will notify you that you are not subject to this Order through CDX correspondence. The EPA expects to provide such notification within 45 days of the effective date of this Order.

To select this option, you must do so within 45 days of the effective date of this Order.

V. OVERVIEW OF TESTING REQUIRED BY THIS ORDER

This unit applies to Option 1: Develop the Information and Option 2: Submit Existing Information (**Units IV.B.1** and **IV.B.2**).

Where the required protocol is an EPA guideline, the guideline is available on the EPA website at http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances[4] and from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-605-6000). This EPA website also provides information on OECD guidelines, which are also available via OECD's website at https://www.oecd.org/chemicalsafety/testing[5]. **Appendix E** provides additional sources for guidelines associated with specific testing.

The EPA reserves the right to revise this Order to extinguish specific testing obligations where existing information subsequently comes to the Agency's attention that in the EPA's scientific judgment obviates the need for specific test data required under this Order. Specific information for ordered test(s) are provided in **Appendix E**.

See **Appendix E** for details on the required test protocols.

Table 3. Entities Responsible and Deadlines for Required Testing Protocol(s)/Methodology(ies)
Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday.

Test Names	Protocols Methodologies	Entities Responsible for Testing	Deadlines to Submit Final Reports to EPA
Environmental Hazard			
Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)	OECD 222 (2016)	Manufacturers	215 days after effective date of the Order
Avian Reproduction Test	OCSPP 850.2300	Manufacturers	295 days after effective date of the Order

[4] *http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances*
[5] *https://www.oecd.org/chemicalsafety/testing*

VI. REQUIREMENTS OF RESPONSE OPTION 1: DEVELOP THE INFORMATION REQUIRED BY THIS ORDER

A. OVERVIEW

The draft study plan is due to the EPA **80 days** after the effective date of this Order. The EPA will then review the draft study plan and provide input to ensure adequacy of the final study plan. For the final study plans and the final test reports, see the Deadlines for Responses, Study Plans, and Test Reports table in **Unit III.A**.

All testing described in **Unit V** must be conducted in accordance with the Good Laboratory Practice (GLP) standards in 40 CFR part 792, as specified in the CFR on the Effective Date of this Order. You must provide a statement of compliance with these GLP standards when submitting information to the EPA pursuant to this Order.

Deviations from the test guideline or specific GLP standards are allowed provided justifications for such deviations are approved by the EPA. A justification is required for each deviation. Justifications should demonstrate that, despite the deviation from the given test guideline or GLP standard, that data integrity, control of bias, and study quality will be maintained with similar effectiveness. Any requested deviations and corresponding justifications must be included in the draft study plan for the Agency's consideration and, if approved, described in the test report.

Once the EPA has completed its review of the submitted test reports and accepts the information as fully complying with your testing obligations under this Order, the Agency will notify you.

B. DRAFT STUDY PLAN REQUIREMENTS

1. Study Plan Requirements for All Categories of Tests

If you choose to develop the required information to comply with this Order, you must obtain and review the required protocols/methodologies. **Unit V** and **Appendix E** provide the protocols/methodologies that must be followed to perform each required test.

If questions and/or issues arise during Study Plan development, the EPA encourages questions/comments be submitted along with the Study Plan submission in accordance with the draft study plan deadline. If the Agency's review of the draft study plan that includes the questions/comments is delayed, the procedure outlined in **Unit III.B** will be followed for automatic extensions of the study plan.

In addition to requirements provided in **Appendix E** for a given test required by this Order, the Study Plans must contain the following information:

1. This Order number, excluding the unique 6-digit company number using X's in place of the unique company number so as to protect each company's private access to the reporting module via Central Data Exchange (CDX). For example, if your Order number is TO-2020-0000-438435-00-0 then provide this number in the Study Plan: TO-2020-0000-XXXXXX-00-0.

2. Name of test to be covered by the test protocol/methodology.

3. The name/number of the protocol/methodology identified in this Order which you intend to follow, a copy of the identified protocol/methodology with your proposed modifications, or a copy of the alternate protocol/methodology you propose to use. Justification(s) must be provided for any deviation from the protocol/methodology provided in this Order.

4. The identity of and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. A Certificate of Analysis of the test substance must be provided.

5. The sampling and analytical method that will be used.

6. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.

7. A description of all quality assurance and quality control protocols used.

8. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.

9. The name(s), mailing address(es), phone number(s), and e-mail address(es) of the appropriate individual(s) for the EPA to contact concerning the planned test.

10. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.

2. Modifying a Required Protocol/Methodology in a Draft Study Plan

The draft study plan must include the required protocols/methodologies outlined in **Unit VI.A.1** and **Appendix E**. If you believe modifications of these required protocols/methodologies are necessary, you should propose the modification in the draft study plan and submit to the EPA with request for the Agency to consider the modifications. Any consultation regarding modifications to the required protocols/methodologies will not extend the deadline for submission of the draft study plan.

Any submitted requests for modifications of the required protocols/methodologies must include a detailed description of the proposed modification as well as a detailed description of the justification and reasoning for such modifications. Requests for modifications of protocol/methodology or the use of an alternate protocol/methodology must discuss why such changes are appropriate and whether they could alter the validity of the study. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant section of the study plan describing the protocols/methodologies.

If the EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before the EPA will approve your study plan. The Agency has 15 days from the deadline for the study

plan to respond. For each day following this period that the EPA does not respond, the Agency will extend the deadline for the final study plan by one day (see **Unit III**).

3. EPA Review of Study Plans and Final Test Report

The EPA will not conduct a substantive review of any draft study plan that does not meet the requirements as provided in **Unit IV.B.1** and **Appendix E**. Such a submission does not constitute meeting the deadline for the draft study plan submission. **Unit III** provides information on deadlines and the EPA response timelines.

Failure to submit a draft study plan, final study plan, and final test report which do not fully comply with the terms of this Order and by the deadlines provided in **Unit III** may result in a violation of TSCA section 15.

a. Study Plans

Following review of a draft study plan submission, the EPA will indicate what modifications, if any, are required and must be incorporated into the final study plan. Accompanying a proposed final study plan submission, the submitter must provide a clean and red-lined version. The red-lined version will indicate the changes incorporated into the final study plan as compared with the draft study plan submission.

If the EPA requires modifications to a submitted draft study plan, the Agency may elect to provide a line-by-line list of comments that must be addressed and corrected before a final study plan will be approved. If the submitter receives a line-by-line list of comments, the submitter must address each individual comment and include this in their response to the Agency along with the proposed final study plan.

Prior to initiating any test, the Company/Consortium must first address the EPA's input on the study plan and receive the Agency's acceptance of the final study plan.

The EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under this Order.

If, after the final study plan has been approved or after testing is underway, you wish to make a modification to an identified protocol/methodology or use a different protocol/methodology, you must submit a request to the EPA to make these changes in your study and you must still meet the deadlines set out in **Unit V** and **Appendix E** for the relevant test or request an extension (see also **Unit III.C**), if needed.

Note that submitting questions to the EPA regarding study plan requirements will not extend the deadline for a study plan submission.

b. Final Test Reports

Once the EPA has completed its initial review and accepted data for all test reports subject to this Order for a given testing requirement, the Agency will notify the designated contact for the company or consortium subject to this Order that this testing requirement has been satisfied, which in turn will close out the testing requirement of this Order for the companies and participants in any consortium subject to

this Order. Failure to file a final test report meeting all the requirements in this Order by the deadline in **Unit III** is a violation of TSCA. Your final test report must be submitted along with the data in the associated Organisation for Economic Co-operation and Development (OECD) harmonized template format, if available. OECD harmonized templates can be located at https://www.oecd.org/ehs/templates/harmonised-templates.htm[6]:

Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222 (2016)

- Harmonized Template Identifier: 50-1

Avian Reproduction Test (OCSPP 850.2300)

- Harmonized Template Identifier: 53

VII. FEES FOR SUBMITTING INFORMATION

Per 40 CFR § 700.45, and taking into account the inflation adjustment that went into effect on January 1, 2022, the Test Order fee is $11,650 to be split evenly among the manufacturers who are required to test a chemical substance or mixture subject to the Test Order (accounting for small business considerations). Processors are not subject to this fee, nor are manufacturers who submit existing information or receive an exemption in compliance with this Order.

Small businesses may be subject to no more than 20% of the amount of the applicable fee. A company may qualify for a "small business concern" discount if their total number of employees is at or below the maximum allowed in the final rule for that company's North American Industry Classification System (NAICS) code (see 40 CFR 700.43). In order for an entity to qualify as a "small business concern," its number of employees shall not exceed the size standard for the applicable industry. When calculating the number of employees, the company must include the employees of all parent and subsidiary companies within the corporate chain. Please note that small business fees are only applicable to qualifying small businesses who are either not associated with a consortium or associated with an all-small business consortium. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses[7].

A company can identify itself as a small business when responding to this Order via the CDX application. The "small business concern" discount will be included in the determination of company-specific invoices for the distribution of the $11,650 fee across all manufacturers conducting testing for the given Test Order. Where a consortium is responsible for the fee for its members for purposes of this Order, and at least one of the members is not a small business, the EPA does not apply a "small business concern" discount to the portion of the $11,650 distributed to the consortium.

Fees for Test Orders under TSCA section 4 will be invoiced electronically by the EPA. Invoice notices will be populated into the specific user's "Copy of Record" screen in CDX and will contain a button that will initiate the payment process. When an invoice is generated, notification e-mails will be sent to the user's CDX inbox and the e-mail address associated with the relevant CDX account. Payment information will be collected in CDX and then submitted to Pay.gov for processing.

[6] *https://www.oecd.org/ehs/templates/harmonised-templates.htm*
[7] *https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses*

Note that there are many fees associated with TSCA-related activities. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-table[8]. The TSCA section 4 Test Order fee is separate from these fees. A company's inclusion in or exclusion from other TSCA fees is unrelated to that company's status with regards to TSCA section 4 Test Order fees.

Pursuant to 40 CFR § 700.45, the applicable fee shall be paid in full no later than 120 days after the effective date of the Order. Should the EPA invoice the fee more than 90 days after the effective date of the Order, payment will be due within 30 days of such invoicing.

VIII. INSTRUCTIONS IF YOU CHOOSE TO PARTICIPATE IN A CONSORTIUM

If you choose to form or join a consortium to share in the cost of developing the required information, you (as well as the other Order recipients who are participants in the consortium) must, individually in the CDX portal, state your intention to participate in a testing consortium for each specific chemical and specific test. Consortium participants must individually respond in the CDX portal with their intent to participate before designated leads are able to add them to the consortium.

In addition, the designated lead for the consortium must submit a consortium response to the EPA in the CDX portal. The response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by indicating each specific test. The response must also include contact information for the designated lead of the consortium, who must be domiciled in the United States. The designated lead for the consortium must submit the response and required information on behalf of the consortium and its member companies by the deadlines listed in **Unit III.A**. Submissions made on behalf of the consortium must be in accordance with instructions in **Appendix C**. Note that a consortium lead need not be a recipient of an Order; other entities (such as trade organizations) may act as a lead and submit the information required under this Order. After the results of the last required test of this Order are submitted and the EPA accepts the information as complying with this Order, or the Agency accepts existing information submitted by the Consortium, the EPA will provide notification of compliance with this Order to this Order's recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with this Order (with the study plan and results being submitted by the consortium) and is individually liable in the event of any failure to comply with this Order. If the consortium fails to submit the information or meet any of the requirements of this Order on your behalf, you will be in violation of this Order unless you submit the required information or meet the requirement individually.

The Agency has provided a list of the manufacturers and processors that have received this Order at the top of this Order in the Summary Information section. This list of manufacturers and processors can be used to help Order Recipients form a consortium to jointly develop information, consolidate testing and share the cost of testing. Information on cost sharing is provided in **Appendix B**.

IX. CONFIDENTIALITY

Under TSCA section 14(b)(2), health and safety studies submitted under TSCA and data reported to or otherwise obtained by the Administrator from health and safety studies are not protected from disclosure if the studies and data concern a chemical that is offered for commercial distribution, or for which

[8] *https://www.epa.gov/tsca-fees/tsca-fees-table*

testing is required under TSCA section 4 or notification is required under TSCA section 5. However, TSCA section 14(b)(2) does not apply to information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised of the chemical subject to this Order. Therefore, some or all of the information in the studies required to be submitted under this Order might not be eligible for TSCA confidential business information (CBI) protections.

Information submitted under TSCA that you wish to have the EPA protect as CBI must be clearly identified as such when submitted. For sections of the report that are claimed as CBI, the report must be accompanied by a sanitized version of the report only removing the specific information claimed as CBI. A sanitized test report that redacts all or most of the study may be rejected by the Agency as not satisfying the requirements of this Order.

When claiming information as CBI, you must certify to the following:

"I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001."

In addition, information claimed as CBI must be substantiated upon submission, with the exception of information described in TSCA section 14(c)(2). Guidance for substantiating CBI claims may be found at https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations.

Failure to follow the statutory requirements for asserting and substantiating a CBI claim may result in the information being made available to the public without further notice to the submitter.

When a claim of CBI under TSCA section 14 is approved by the EPA, the Administrator will generally protect that information from disclosure for 10 years (unless the protection from disclosure is withdrawn by the person that asserted the claim), whereupon the claim must be reasserted and re-substantiated if the submitter wishes to maintain the CBI claim. In certain cases, the Agency may review claims prior to the expiration of the 10-year period.

Under circumstances stated in TSCA section 14(d), the EPA may disclose information claimed as CBI to other persons including, for example, Federal and State authorities, health and environmental professionals, poison control centers, and emergency responders.

X. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS ORDER

Failure to comply with any of the requirements in this Order is a violation of TSCA section 15 and could subject you to civil and/or criminal penalties under TSCA section 16, 15 U.S.C. § 2615 as modified by the Federal Civil Penalties Inflation Adjustment Act. Each day that failure to meet the requirements continues constitutes a separate violation.

XI. REFERENCES

The following is a listing of the documents that are generally applicable to this Order. **Appendix E** provides references specific to certain testing requirements in this Order. Please note that references, guidance, and information from additional sources could be considered, with EPA approval, during the development of study plans.

The docket includes these documents and other information considered by the EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

General References for this Test Order

1. U.S. EPA (2021). 1,1,2-Trichloroethane Test Order [EPA-HQ-OPPT-2018-0421]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane[9]

2. U.S. EPA (2020a). Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane [EPA-740-R-20-003]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf[10]

3. U.S. EPA (2020b). Use Report for 1,1,2-Trichloroethane (CASRN 79-00-5) [EPA-HQ-OPPT-2018-042]. Washington DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT). https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0421-0018[11]

Earthworm Reproduction (*Eisenia fetida/Eisenia andrei*) Test References

[9] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane*
[10] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf*
[11] *https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0421-0018*

4. OECD. (2016). Test No. 222: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*). Paris, France: OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing. https://doi.org/10.1787/9789264264496-en[12]

Avian Reproduction Test References

5. Elovaara, E., Hemminki, K., Vainio, H. (1979). Effects of Methylene Chloride, Trichloroethane, Trichloroethylene, Tetrachloroethylene and Toluene on the Development of Chick Embryos. Toxicology, Volume 12, Issue 2, Pages 111-119, ISSN 0300-483X. https://doi.org/10.1016/0300-483X(79)90037-4[13]

6. U.S. EPA (2012). OCSPP 850.2300: Avian Reproduction Test [EPA 712C-023]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012[14]

7. U.S. EPA (2020). Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis. Washington DC: U.S. Environmental Protection Agency, Office of Pesticide Programs (OPP). https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf[15]

8. U.S. Geological Survey (USGS). (1991). USGS Monitoring Data: National Water Quality Monitoring Council [Database] – Air, Groundwater, Sediment, Soil, Surface Water, Tissue. http://www.waterqualitydata.us/portal/[16]

XII. PAPERWORK REDUCTION ACT NOTICE

This collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. (OMB Control No. 2070-0033). Responses to this collection of information are mandatory under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 137 hours for the average response on a per-chemical basis. Under the PRA, burden is defined at 5 CFR 1320.3(b). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

XIII. FOR FURTHER INFORMATION CONTACT

For technical information contact: TSCATestOrders@epa.gov.

[12] *https://doi.org/10.1787/9789264264496-en*
[13] *https://doi.org/10.1016/0300-483X(79)90037-4*
[14] *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012*
[15] *https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf*
[16] *http://www.waterqualitydata.us/portal/*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

XIV. SIGNATURE

Under the authority in TSCA section 4(a)(2), the United States Environmental Protection Agency hereby issues this Order to take effect on the date of my signature.

MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF Date: 2022.03.24 06:46:32 -04'00'

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Enclosures

APPENDIX A - EQUIVALENCE DATA

For purposes of this Order, "equivalence data" means "chemical data or biological test data intended to show that two substances or mixtures are equivalent." Also, when a chemical substance is "equivalent," it means "that a chemical substance is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance," as defined in 40 CFR § 790.3.

If testing under TSCA section 4(a) is required of an equivalent chemical substance, the EPA may grant an exemption from testing to the manufacturer or processor of one substance if the information required under TSCA section 4(a) is submitted or is being developed on the other, and the manufacturer or processor submits the following information to support equivalence with its exemption application:

1. The chemical identity of each chemical substance or mixture manufactured or processed by the applicant for which the exemption is sought. The exact type of identifying data required may be specified in this Order and may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

2. The basis for the applicant's belief that the substance or mixture for which the exemption is sought is equivalent to the test substance or mixture.

3. Any other data which exemption applicants are directed to submit in this Order which may have bearing on a determination of equivalence. This may include a description of the process by which each chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

APPENDIX B - COST SHARING

The EPA encourages Order recipients that are responsible for developing the same information on the same chemical(s) to avoid duplicative testing and share the cost of information development. If a test is conducted according to a final, approved protocol, it is sufficient that the test is conducted once. Two ways to avoid duplicative testing are discussed in this Order. They are forming or joining a consortium, discussed in **Unit VIII**, or requesting an exemption, discussed in **Unit IV.B.3**.

Consortia

Persons that form or join a consortium typically execute an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate.

Exemptions

Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the testing and submit the required information that is the basis for the exemption for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is ideally negotiated between the companies involved, without the EPA's participation. The Agency has promulgated regulations that explain how the EPA views fair and equitable reimbursement in the context of TSCA section 4(a) test rules. In general, those regulations (40 CFR § 791.40 through § 791.52) make a presumption that a person's fair share of the test costs is in proportion to their share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations do not apply to TSCA section 4 orders, you may wish to consider them as you decide how to share the costs.

If persons subject to an order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the person whose information is the basis for the exemption may request that the Administrator order the person(s) granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA section 4(c)(3)(A). Upon receipt of such a request, the EPA will determine fair and equitable reimbursement and issue an order accordingly. The Agency may, at its discretion, make use of procedures and standards applicable to data reimbursement regarding TSCA section 4 rules, contained in 40 CFR part 791.

APPENDIX C - HOW TO ACCESS THE CDX APPLICATION AND RECORDKEEPING REQUIREMENTS

How to Access the CDX Application

The initial response, draft and final study plans, final test reports with underlying data, existing studies, any testing related requests, and all related correspondence must be submitted electronically to the EPA as follows:

1. Submit to the EPA's CDX system. CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for submissions to the Agency.

2. The URL for the CDX website is *https://cdx.epa.gov/*[17] which takes you to the CDX homepage.

3. On the homepage you may select "Log in" or, if you haven't already registered, select "Register with CDX."

4. Once you have logged on to CDX, follow the instructions for submitting TSCA section 4 order information. To access the instructions, select "Report electronically" on the EPA Internet homepage at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*[18].

5. The CDX Help Desk is available for data submission technical support between the hours of 8:00 am and 6:00 pm (EST) at 1-888-890-1995 or helpdesk@epacdx.net. The CDX Help Desk can also be reached at 970-494-5500 for international callers.

The EPA may revise these submission instructions with advance notice.

Recordkeeping

You must retain copies of all information documenting your compliance with this Order for ten years. This includes your response and other documents and correspondence submitted to comply with this Order, such as test protocols, testing related requests, final test reports with their underlying data, and any penalties remitted.

[17] *https://cdx.epa.gov/*
[18] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*

APPENDIX D - ORDER RECIPIENT SELECTION

This Appendix describes the process by which the EPA identified recipients of this Order. This information is for your use, and does not govern the obligations under this Order or the identities of the companies subject to this Order. A recipient of this Order that manufactures or processes the chemical as per the definitions provided in **Unit I.B** is subject to this Order, regardless of the basis on which the Agency identified the recipient.

The manufacturers and processors of the chemical subject to this Order were determined in the following manner:

The EPA included in this Order as recipients all companies comprising the final list of manufacturers subject to fee payments[19] for *p*-dichlorobenzene developed under the "Fees for Administration of Toxic Substances Control Act" rule in 2020, as well as, manufacturers identified by other sources, including Toxics Release Inventory[20] (TRI) reporting from 2016 to 2020 and Chemical Data Reporting (CDR) reporting from 2020. The Agency also included in this Order Companies who reported as "Processors" of this chemical to the 2016 to 2020 TRI. Although the EPA recognizes that there are processors who do not report to TRI, this database was used to identify processors for the purposes of this order because it is the Agency's most comprehensive source to establish a well-verified list of processing companies.

[19] *https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations*
[20] *https://www.epa.gov/toxics-release-inventory-tri-program*

APPENDIX E - SPECIFIC REQUIREMENTS AND GUIDANCE FOR THIS ORDER

This appendix provides requirements of study plans and test reports for specific testing requirements of this Order. Additionally, this appendix provides additional reference material(s) associated with the testing required in this Order.

For information on how the EPA determined the need for the testing requirements of this Order, refer to **Unit II.B.**

I. Environmental Hazard

a. Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222 (2016)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to OECD 222 include:

1. Final exposure concentrations must capture both lethal and sub-lethal effects over a period of 8-weeks, such that they bracket the Effective Concentration (ECx) estimate. To ensure these requirements are met, it is highly recommended that a range finding test is conducted before the initiation of the definitive test.

2. Soil must be mixed and homogenized with the chemical, and the source, purity, and a Certificate of Analysis of the test substance must be reported. The draft study plan will not be approved by the EPA without the purity of the test material.

3. The analytical laboratory must describe how they will conduct analytical verification of the test material at the beginning and end of the test, and every 7-days throughout the test duration.

4. A description must be provided as to whether the use of formulated/artificial or field-collected soil is being implemented (the EPA recommends formulated/artificial soil).

5. An outline must be provided of the raw data to be collected for each sub-lethal and lethal endpoint as well as statistical analyses that are planned.

6. Because 1,1,2-trichloroethane is a volatile substance, a description must be provided as to how the test laboratory will account for volatilization.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 215 days after effective date of the Order and must include the following, as applicable:

1. Harmonized Template ID: 50-1

2. Harmonized Template URL: https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm[21]

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. OECD (Organisation for Economic Co-operation and Development). (2016). Test No. 222: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*). Paris, France: OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing. https://doi.org/10.1787/9789264264496-en[22]

b. Avian Reproduction Test (OCSPP 850.2300)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to OCSPP 850.2300 include:

1. An outline must be provided of the raw data to be collected for each sub-lethal and lethal endpoint as well as statistical analyses that are planned.

2. The study laboratory must describe how they will conduct analytical verification of the test material in the diet at the beginning, middle and end of the test to ensure exposure, and the source, purity, and a Certificate of Analysis of the test substance must be reported. The draft study plan will not be approved by the EPA without the purity of the test material.

3. A description should be provided as to how frequently the test diets will be mixed, to ensure for volatile substance that the concentrations are not reduced from initial concentrations by more than 20%.

4. The Northern bobwhite (*Colinus virginianus*) must be used instead of the mallard (*Anas platyrhynchos*) or other test species recommended in the guideline, because it is less prone to regurgitation and easier to measure food consumption for this species.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 295 days after effective date of the Order and must include the following, as applicable:

1. Harmonized Template ID: 53

2. Harmonized Template URL: https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm[23]

[21] *https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm*
[22] *https://doi.org/10.1787/9789264264496-en*
[23] *https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm*

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. Elovaara, E., Hemminki, K., Vainio, H. (1979). Effects of Methylene Chloride, Trichloroethane, Trichloroethylene, Tetrachloroethylene and Toluene on the Development of Chick Embryos. Toxicology, Volume 12, Issue 2, Pages 111-119, ISSN 0300-483X. https://doi.org/10.1016/0300-483X(79)90037-4[24]

2. U.S. EPA (2012). OCSPP 850.2300: Avian Reproduction Test [EPA 712C-023]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012[25]

3. U.S. EPA (2020). Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis. Washington DC: U.S. Environmental Protection Agency, Office of Pesticide Programs (OPP). https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf[26]

4. USGS. (1991). USGS Monitoring Data: National Water Quality Monitoring Council [Database] – Air, Groundwater, Sediment, Soil, Surface Water, Tissue. http://www.waterqualitydata.us/portal/[27]

[24] *https://doi.org/10.1016/0300-483X(79)90037-4*
[25] *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012*
[26] *https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf*
[27] *http://www.waterqualitydata.us/portal/*

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

VINYL INSTITUTE, INC.,	)	
	)	
Petitioner,	)	
	)	
v.	)	
	)	Case No. 22-1089
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,	)	
	)	
Respondent.	)	
	)	
	)	
	)	

FILING OF UNDERLYING DECISION BY PETITIONER

Pursuant to this Court's Order dated May 24, 2022, Petitioner through its undersigned counsel hereby files the agency action on appeal.

Dated June 23, 2022

/s/ Eric P. Gotting
Eric P. Gotting
Peter L. de la Cruz
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
Phone: (202) 434-4100
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Email: gotting@khlaw.com
Email: delacruz@khlaw.com
Counsel for Vinyl Institute, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2022, I electronically filed the forgoing document with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Eric P. Gotting

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 20, 2022

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

Correction to Order Under (4)(a)(2) of the Toxic Substances Control Act

EPA is issuing a correction of the TSCA section 4(a)(2) Test Order for 1,1,2-trichloroethane signed on March 24, 2022, with an effective date of March 29, 2022.

Correction:

EPA is amending Appendix D – Order Recipient Selection. Appendix D referred to *p*-dichlorobenzene, although it should have referred to 1,1,2-trichloroethane. Appendix D only explains the process for identifying order recipients. This correction does not change the obligations that apply to manufacturers and processors of 1,1,2-trichloroethane, pursuant to TSCA section 4(a)(2). EPA identified the recipients of this Order through those sources related to manufacturers and processors of 1,1,2-trichloroethane.

Under the authority in TSCA section 4(a)(2), the United States Environmental Protection Agency hereby modifies this Order as described above. All other terms and conditions in the original Order shall remain in effect.

Michal Freedhoff, MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF Date: 2022.04.20 11:29:34 -04'00'

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 24, 2022

Order Under Section 4(a)(2) of the Toxic Substances Control Act

Chemical Substance Subject to this Order:

Chemical Name: 1,1,2-Trichloroethane

Chemical Abstracts Service Registry Number (CASRN): 79-00-5

Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0421[1]

Testing Required by this Order:

1. Environmental Hazard
    - Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
    - Avian Reproduction Test

Recipients of this Order:

Company Name: C-K TECH INC

Company Name: KEM KREST LLC

Company Name: FORMOSA PLASTICS CORP USA

Company Name: HAAS GROUP INTERNATIONAL

Company Name: OCCIDENTAL CHEMICAL HOLDING CORP

Company Name: OLIN CORP

Company Name: WESTLAKE CHEMICAL CORP

Dear Recipient:

This Order requires you and the other named manufacturer(s) and/or processor(s) of 1,1,2-trichloroethane (CASRN 79-00-5) to develop and submit certain information for 1,1,2-trichloroethane, or otherwise respond to the U.S. Environmental Protection Agency (referred to herein as "the EPA" or "the Agency"). Failure to respond to this Order, or failure to otherwise comply with its requirements, is a violation of section 15 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2614. Any person

[1] To access the docket, go to https://www.regulations.gov.

who violates TSCA shall be liable to the United States for penalties in accordance with TSCA section 16, 15 U.S.C. § 2615.

This Order is **effective 5 calendar days after its date of signature by the EPA**. The timeframes and options for responding are described in **Unit IV** (Response Options). Please note that the email transmitting this Order to you will provide the calendar date for the response deadlines as defined in **Unit III** (Deadlines for Responding to this Order). A subsequent email will provide a company specific Order number for you to use in responses and communications about this Order.

This Order is organized as follows:

I. PURPOSE AND AUTHORITY

A. OVERVIEW

This Order is being issued under the authority of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. TSCA section 4 authorizes the EPA to require the development of necessary information related to chemical substances and mixtures.

This Order requires the identified recipients to develop and submit new information on 1,1,2-trichloroethane (CASRN 79-00-5) that is necessary for the EPA to perform a risk evaluation under TSCA section 6(b).

Information on testing requirements is provided in **Appendix E**. The EPA encourages the formation of industry consortia to jointly conduct testing between the recipients of this Order. See **Unit VIII** for more information on this topic.

The Order provides four response options, listed below. More information on each of these options is provided in **Unit IV**. Timeframes for these options is provided in **Unit III**. Note that the deadline to identify as a manufacturer, processor, or both is 30 calendar days of the effective date of this Order. This step is necessary for purposes of this Order to ensure that your company can appropriately access the CDX application used for responding to section 4 orders.

Option 1: Develop the Information
Use this option to develop information in response to all of the requirements of this Order that apply to you, or use this option in conjunction with other response options identified in this section as appropriate.

Manufacturers who are required to test a chemical substance or mixture pursuant to a TSCA section 4 order are also required to pay a fee (see **Unit VII**).

Option 2: Submit Existing Information
Use this option to submit an existing study and/or other scientifically relevant information that you believe the EPA has not considered, along with supporting rationale that explains how the submittal(s) meets part or all of the information described as necessary in **Unit II**. If the Agency determines that the submitted information satisfies one or more data needs identified by this Order, the Agency will extinguish any associated test requirement(s).

Option 3: Request an Exemption
Use this option to request an exemption from a testing requirement of this Order. The EPA will grant an exemption if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement; and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

Option 4: Claim that You Are Not Subject to this Order
Use this option to claim that you are not subject to this Order. You may claim that you are not subject to this Order if all of the following are true:

1. You do not currently manufacture or process the chemical(s) identified by this Order;

2. You do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order; and

3. You have not manufactured or processed the chemical(s) at any time during the five years preceding the date of this Order.

You must provide an explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim.

B. Terminology Used in this Order

The term "manufacture" means to import into the customs territory of the United States, to produce, or to manufacture. 15 U.S.C. § 2602(9). Import also includes importing the chemical as an impurity in an article.

The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture. 15 U.S.C. § 2602(13).

The term "chemical" or "substance" means a chemical substance or mixture.

C. Persons Subject to this Order

1. Persons Identified

An order issued under section 4(a) of TSCA may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the order. The recipients of this Order are listed at the top of the Order.

For purposes of this Order, a recipient identified by this Order is subject to the Order if it has manufactured or processed the chemical at any time during the five years preceding the date of this Order. If a recipient identified by this Order has not manufactured or processed the chemical during the prior five years, the recipient is nevertheless subject to the Order if they intend to manufacture or process the chemical within the period of testing provided by this Order.

A person who contracts with a producing manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the producing manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

A recipient who is an importer of record of a chemical substance identified by this Order is responsible for the testing requirements of this Order, even if the recipient does not store, handle, use, or otherwise directly deal with the chemical.

The means by which the EPA identified each recipient subject to this Order does not govern whether a recipient is subject to this Order. Ultimately, any recipient that meets the criteria discussed in this section is subject to this Order, regardless of the basis on which the Agency identified the recipient.

2. Corporate Structure of Recipients: Changes of Ownership

The EPA has attempted to identify the highest-level U.S. corporate entity for purposes of issuing this Order. The highest-level U.S. corporate entity is ultimately responsible for satisfying the obligations of this Order, although the highest-level U.S. corporate entity may delegate its responsibilities under this Order to a U.S. subsidiary. Where the corporate entity named in this Order is not the highest-level U.S. corporate entity, the Agency nonetheless considers notification of the company named in this Order to

constitute notification of the highest-level U.S. corporate entity and holds the highest-level U.S. corporate entity ultimately responsible for satisfying the obligations of this Order.

Should you wish to modify the name of the recipient or identify another U.S. corporate entity in the corporate structure as the point of contact in place of the recipient named in this Order, you must submit a request to the EPA. Submit your request, justification for the change, and contact information for the representatives of the newly named entity to TSCAtestorders@epa.gov. A representative from the Agency will contact you and any other representatives regarding this request.

In the event of mergers, acquisitions, or other transactions that create a corporate successor in interest (subsequent to the manufacturing or processing that triggered the reporting obligation, and either before or after receipt of this Order), that successor in interest is responsible for satisfying the obligations of this Order. The successor in interest must notify the EPA of its identity within 14 days following the transaction.

D. Previously Issued Orders

The EPA previously issued a test order for 1,1,2-trichloroethane, effective January 19, 2021, to meet other data needs. See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane[2].

Since issuing that test order, the EPA's continuing review of the reasonably available information has identified additional information needed to inform the associated risk evaluation. Accordingly, the Agency is issuing this additional Order for 1,1,2-trichloroethane. See the Statement of Need for further details. This Order does not alter the requirements of any previous test orders.

II. STATEMENT OF NEED

The basis for requiring the development of new information by this Order is described in this unit and in **Appendix E**. This statement of need, as required by TSCA section 4(a)(3), includes: (A) the need for the new information; (B) how information reasonably available to the Administrator was used to inform the decision to require the new information; (C) why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement; and (D) (if applicable) the basis for the Agency's decision to require testing of vertebrate animals. **Appendix E** (Testing Requirements of This Order) indicates which tests apply specifically to manufacturers and/or processors subject to this Order.

A. The Need for the New Information

This section and **Appendix E** explain what new information is being required in this Order and why such information is needed for the risk evaluation of 1,1,2-trichloroethane under TSCA section 6(b).

The EPA has identified the following information in this section as necessary to conduct a risk evaluation to determine whether 1,1,2-trichloroethane presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use (COU).

[2] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane*

The next unit will outline how the EPA came to determine these new information needs. Note that additional details for these testing requirements are provided in **Unit V** and **Appendix E**.

1. Environmental Hazard

Information on hazards to aquatic and terrestrial organisms is needed to conduct a risk evaluation. The relevant environmental hazard data needs that this Order seeks to address for 1,1,2-trichloroethane, as described below, are as follows:

- Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
- Avian Reproduction Test

B. How Information Reasonably Available to the Administrator Was Used to Inform The Decision to Require New Information

This section details the "Scoping and Conceptual Models" and "Systematic Review of Reasonably Available Existing Information" processes used by the EPA to identify, respectively, what information is reasonably available to integrate into the risk evaluation for the conditions of use of 1,1,2-trichloroethane and ascertain, via a "Discipline-Specific Approach for Identifying Data Needs" what needed information is not reasonably available in existing literature (i.e., what testing to require).

1. Scoping and Conceptual Models

The *Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane* (https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf[3]) (hereinafter "*Final Scope*") includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane. The Agency has used the scope document and the conceptual models therein for workers and occupational non-users (ONUs), consumers and bystanders, general population, and environmental releases as a starting point for identifying information needs under this Order. The conceptual models visually represent the human and environmental exposures (pathways and routes), receptors, and hazards associated with the conditions of use of 1,1,2-trichloroethane. For each exposure (pathway and route), receptor, and hazard that is visually represented, the EPA has identified the information needed to conduct a risk evaluation for this chemical.

In addition, since publication of the *Final Scope*, the EPA has reconsidered the policy decision to exclude from the scope of TSCA section 6(b) risk evaluations certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. Based on that reconsideration, the Agency now also intends to consider in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane all of the exposure pathways portrayed in Figure 2-15 (Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)) of the *Final Scope*, and has identified the information needed for that assessment.

2. Systematic Review of Reasonably Available Existing Information

The systematic review process began with searching peer-reviewed literature databases (*e.g.*, Agricola, PubMed, Science Direct, ECOTOX Knowledgebase) for studies using 1,1,2-trichloroethane, synonyms,

[3] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf*

and trade names. The EPA also conducted a search of gray literature (*e.g.*, technical reports, reference books, dissertations, and other information not found in standard, peer-reviewed literature databases), as well as review of public comments posted to the docket for this chemical substance during the prioritization process and following publication of the draft scope document, relevant data and information submitted to the Agency under TSCA sections 4, 5, 8(e), 8(d), and For Your Information (FYI) submissions. The collected compilation of information was then screened for relevance. This process applied title/abstract screening and/or full-text screening based on screening criteria developed *a priori* for environmental hazard and consumer exposure (Population, Exposure, Comparator and Outcomes (PECO)); physical and chemical properties (Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO)) or occupational exposure literature (Receptors, Exposure, Setting or Scenario, and Outcomes (RESO)).

3. Discipline-Specific Approach for Identifying Data Needs

a. Environmental Hazard

The EPA defined the pathways and routes of exposure, receptors, and hazards for environmental releases and wastes that are expected to be evaluated in the *Final Scope* (Figure 2-15 pg. 44). As noted above, since publication of the *Final Scope*, the Agency has reconsidered the policy decision to exclude from the scope of TSCA section 6(b) risk evaluations certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. The Agency intends to consider all aquatic and terrestrial exposure pathways in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane, and has identified the information needed for that assessment.

As determined in the *Final Scope*, the manufacturing, processing, distribution, use and disposal of 1,1,2-trichloroethane can result in releases to the environment and exposure to aquatic and terrestrial organisms. The EPA expects to assess environmental hazards and risks to both aquatic and terrestrial plants, invertebrates, and vertebrates and therefore requires hazard data for each of these assessment endpoints. The Agency also expects to assess organisms for both aquatic and terrestrial hazard when those organisms transition between aquatic and terrestrial ecosystems depending on the life stage evaluated (e.g., midges inhabit sediment as larvae but mature into adults that inhabit terrestrial and aquatic ecosystems).

Identification of the reasonably available information for 1,1,2-trichloroethane included consideration of existing data for the parent chemical and analogous chemicals for aquatic and terrestrial exposure pathways. The EPA identified seven analogues to 1,1,2-trichloroethane using EPA's Analog Identification Methodology (AIM) software (see **Unit II.B, Environmental Hazard – Analogues Table**). The Agency identified existing measured environmental hazard data for aquatic and terrestrial species for 1,1,2-trichloroethane and the identified analogues from the EPA's ECOTOX Knowledgebase (ECOTOX) and information submitted under TSCA, (e.g., under Sections 4 and 8e), FIFRA, and the Endocrine Disruptor Screening Program (EDSP).

Pursuant to this Order, the EPA is requiring data be submitted to facilitate evaluation of risk to terrestrial organisms. An order requesting testing to fill the aquatic data gaps identified for 1,1,2-trichloroethane was issued previously (see **Unit XI, References**). As shown in the table below, terrestrial environmental hazard data were identified for 1,1,2-trichloroethane and two of the seven identified analogues. These data covered exposures of 1,1,2-trichloroethane to terrestrial vegetation, acute exposures to soil invertebrates, mammals, and birds, and chronic exposures to mammals. No toxicity data for chronic exposures to soil invertebrates or birds were identified.

Table 1. Terrestrial Environmental Hazard – Analogues

Chemical Name	CASRN	Environmental Hazard Data Availability for 1,1,2-Trichloroethane						
		Acute Exposure			Chronic Exposure			Vegetation
		Soil Invertebrate	Mammal	Bird	Soil Invertebrate	Mammal	Bird	
1,1,2-Trichloroethane	79-00-5	X	X	X	-	X	-	X
Analogues for 1,1,2-Trichloroethane								
1,1,1-Trichloroethane	791-55-6	X	X	X	-	-	-	X
Trichloroethane	25323-89-1	-	-	-	-	-	-	-
1,2,3-Trichloropropane	96-18-4	-	X	-	-	-	-	-
1,2,3,4-Tetrachlorobuta-1,3-Diene	1637-31-6	-	-	-	-	-	-	-
1,1,5,5-Tetrachloropentane	17655-64-0	-	-	-	-	-	-	-
1,1,2,3-Tetrachloropropane	18495-30-2	-	-	-	-	-	-	-
1,2,3,4-Tetrachlorobutane	3405-32-1	-	-	-	-	-	-	-

X signifies data were identified and "-" signifies a gap, where no data were identified

C. Why Issuance of this Order is Warranted Instead of Promulgating a Rule or Entering Into a Consent Agreement

The EPA is using its order authority under TSCA section 4(a)(2) to inform the risk evaluation for 1,1,2-trichloroethane under TSCA section 6(b) in accordance with the requirements and timeframes for conducting the risk evaluation. Use of this TSCA section 4(a)(2) authority will allow the Agency to target known manufacturer and processor recipients to obtain the needed information more quickly than if the EPA were to issue a TSCA section 4 rulemaking or consent agreement.

D. The EPA Determined that Vertebrate Testing is Needed in this Order

The EPA has determined that vertebrate testing is needed to assess the particular exposure pathways and receptors discussed in this Order. Reasonably available data, computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing required by this Order (see below for details). The analysis for determining data needs described in **Unit II.B** included use of acceptable new approach methodologies (NAMs), specifically the EPA computational toxicology and informatics tools such as AIM, to identify analogues with existing information that could potentially fill data needs. A list of the testing on vertebrates required by this Order as well as further information on the EPA review process that led to the inclusion of such testing requirements can be found in **Unit II.B** and **Appendix E**, as well as below.

1. Environmental Hazard: Avian Reproduction Test

No avian toxicity data following chronic exposures were identified for 1,1,2-trichlorethane or identified analogues for any endpoints. No approved or readily available new approach methodologies (NAMS) were identified that could be used to inform the data gap for avian toxicity following chronic exposure. Without toxicity data, the EPA is unable to determine if chronic exposures to 1,1,2-trichlorethane pose a risk to terrestrial vertebrates. Office of Pesticide Programs recently released a guidance that describes instances where sub-acute dietary testing in birds may be waived (U.S. EPA, 2020). This waiver specifically outlines instances where the

animal testing burden can be reduced by requesting only acute testing oral testing in birds and waiving the traditional requirement for both acute oral testing and sub-acute dietary testing with avian species. As this Test Order does not request acute oral testing with birds nor sub-acute dietary testing with birds, this waiver request is not relevant. The Agency has worked to ensure that the animal testing burden under TSCA is reduced by utilizing all available ecotoxicity data and tailoring data needs to the specific properties of each chemical. The testing requirement is reinforced by avian toxicity data captured in the peer-reviewed literature undergoing systematic review, which qualitatively indicates exposure to 1,1,2-trichloroethane caused developmental toxicity to chick embryos (Elovaara, 1979). While the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure, the evidence of teratogenicity in chick embryos indicates that additional data are needed to understand the potential effect following chronic dietary exposure. Monitoring data from USGS's National Water Quality Monitoring Council has also identified 1,1,2-trichloroethane in media to which terrestrial vertebrates could be exposed, including ground water, sediment, soil, surface water and biota (USGS, 1991).

III. DEADLINES FOR RESPONDING TO THIS ORDER

This section describes the deadlines for this Order and possible modifications to such deadlines.

A. DEADLINES FOR RESPONSES TO THIS ORDER

The table below provides the deadlines for this Order. Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday. Descriptions of these response options and the required process associated with each option is provided in **Unit IV**.

Table 2. Deadlines for Responses, Study Plans, and Test Reports

Order Requirement	Recipient's Deadline (Days after the effective date of the Order)	EPA Response Deadline*
• Identify as a Manufacturer, Processor or Both	30	n/a
• Submit Request to Modify Corporate Identity Identified	30	n/a
• Choose to Submit Existing Data (Option 2)	30	45
• Claim that You Are Not Subject to this Order (Option 4)	45	60
• Choose to Develop the Information - On Own or as Part of a Consortium (Option 1)	65	n/a
• Request an Exemption (Option 3)	65	80
• Submit Draft Study Plan	80	95
• Submit Final Study Plan	110	125
• Submit Final Test Report	Deadline varies per Test Requirement (See **Unit V** and **Appendix E**)	

*See **Unit III.B** for potential automatic extensions associated with the EPA responses. Deadlines for submitting final test reports for each required test are provided in **Appendix E**.

B. AUTOMATIC EXTENSIONS TO DEADLINES

The EPA will automatically extend deadlines should the Agency fail to meet any EPA response deadline set forth in **Unit III.A**. Specifically, deadlines will be automatically extended should the

Agency fail to respond within 15 calendar days of the deadline for a response option if the response was submitted in the CDX application prior to the deadline provided. For each day exceeding the 15-day period following the associated deadline, the EPA will extend subsequent deadlines by one day.

Should a recipient amend their response, at any time, the EPA will not extend any associated or subsequent deadlines. Therefore, the Agency recommends that recipients submit their amendments or extension requests as early as practicable to ensure adequate time to perform any required testing given that the Agency will not automatically extend deadlines for any such amendments to responses.

The EPA will not automatically extend a deadline for a response should the recipient submit its response after the deadline for the given response option. Additionally, the EPA will not automatically extend a deadline for a response should the Agency respond within 15 days of the deadline for a given response option that was submitted on or before the deadline for that response option.

Other than potential automatic extensions to deadlines described here, **Unit III.C** provides the process for requesting an extension to a deadline.

C. Requesting An Extension To A Deadline For Responding To This Order

If you believe you cannot submit the required identification as a manufacturer, processor, or both; Order response; draft study plan; final study plan; or final test report to the EPA by the deadline(s) specified in this Order and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency through the EPA's CDX portal as soon as you know you may need an extension. Your request must include: (1) a detailed description of the expected difficulty, including technical and laboratory difficulties, and (2) a proposed schedule including alternative dates for meeting such requirement(s) on a step-by-step basis.

The EPA will grant or deny deadline extension requests at its discretion.

IV. RESPONDING TO THIS ORDER

You are required to respond to this Order even if you believe your company is not subject to this Order. Failure to provide a response is a violation of section 15 of TSCA.

A. Identify As A Manufacturer, Processor, Or Both

Within 30 calendar days of the effective date of this Order, you, as a recipient of this Order, are required to respond to this Order through the EPA's Central Data Exchange (CDX) portal, informing the Agency whether you will be responding to this Order as manufacturer or processor (if you manufacture and process the chemical, select manufacturer). To provide your preliminary response to this Order, you will receive an e-mail from the EPA within five days of the Order being signed (i.e., by the effective date of the Order) that provides a CDX Order number for purposes of complying with this Order.

You may claim that you are not subject to this Order if you (1) do not currently manufacture or process the chemical(s) identified by this Order; (2) do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and (3) have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order. See **Unit VI.B.4** for more information on how to claim that you are not subject to this Order.

B. Four Response Options

A recipient has four available options for purposes of responding to this Order. See **Unit III** to review the deadlines for this Order.

Option 1: Develop the Information

If you choose to develop information in response to this Order, you must select this option in the CDX portal form.

For details on the steps of this response option, see **Unit VI**.

For more information on this Order's required tests, required protocols/methodologies, and deadlines for submission of test reports see **Unit V** and **Appendix E**.

Option 2: Submit Existing Information

If you choose to respond to this Order by submitting an existing study and/or other scientifically relevant information that you believe the EPA has not considered, your response in the EPA's CDX portal must be submitted to the EPA 30 days after the effective date of the Order and include the study(ies) and/or other scientifically relevant information, along with supporting rationale that explains how the study and/or other scientifically relevant information meets part or all of the information or obviates the need for the information described as necessary in **Unit II**.

The EPA's determination regarding whether the study and/or other relevant information satisfies part or all of the information or obviates the need for the information described as necessary in **Unit II** will be based on the weight of the scientific evidence from all relevant information reasonably available to the Agency. The Agency will notify you of its determination through CDX. If the Agency determines that the study and/or other scientifically relevant information satisfies the need in lieu of the testing required in this Order and/or the original testing requirement is no longer needed, the EPA will extinguish those testing obligations from this Order that are no longer necessary, with respect to the appropriate recipients of this Order. If the study was your only testing obligation under the Order, all your obligations under this Order will be extinguished upon notification by the Agency.

If the EPA determines that the study and/or other scientifically relevant information does not satisfy that need, you must modify your response in the EPA's CDX portal to choose one of the other response options in **Unit IV** within 10 calendar days of being notified by the Agency.

Note that the submission of existing information will not extend the deadline for the draft study plan submission for that testing requirement unless the existing information is submitted within 30 days of the effective date of the Order and the EPA does not respond within 45 days of the effective date of the Order. Thus, failure to submit existing information prior to the 30-day deadline will result in a need to submit a draft study plan by the 80-day deadline. See Unit **III.B** for information on the potential automatic extension of deadlines.

Option 3: Request an Exemption

Any person required by this Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA section 4(c)(1)).

The EPA will grant a request for exemption from the requirement to conduct tests and submit information on a chemical substance if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement, and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

An exemption request must be submitted through the CDX portal and contain the following:

1. This Order number, the chemical identity, and the CAS Registry No. of the test substance subject to this Order on which the application is based.

2. The specific testing requirement(s) from which an exemption is sought.

3. The basis for the exemption request when another company(ies) has/have submitted the information or is/are developing information for the subject chemical or an equivalent chemical pursuant to a TSCA section 4(a) rule, order, or consent agreement. Your request must identify the company(ies) that submitted or is/are developing the information.

4. The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.

5. The equivalence data ("chemical data or biological test data intended to show that two substances or mixtures are equivalent" (see **Appendix A**)), if data on an equivalent chemical is being submitted.

6. The name, mailing address, telephone number, and e-mail address of applicant.

7. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.

8. A Statement of Financial Responsibility: The following sworn statement (i.e., signed and notarized) must accompany each request for an exemption:

> "I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based."

The EPA's grant of an exemption is conditional upon the completion of the required tests according to the specifications of this Order (or other applicable rule, order, or consent agreement), including any modifications approved by the Agency. If the EPA subsequently determines that equivalent data has not been submitted in accordance with the applicable rule, order, or consent agreement, the Agency will provide notice through CDX of its preliminary decision to terminate the exemption. Within 30 days after receipt of such notice, the exemption holder may submit information in the CDX portal either to rebut the EPA's preliminary decision to terminate the exemption or notify the Agency of its intent to develop

the required information pursuant to the specifications established in this Order and any modifications approved by the EPA. If the exemption holder submits information to rebut the EPA's preliminary decision to terminate the exemption, then the Agency will provide the exemption holder an opportunity to request a hearing prior to issuing a final decision to terminate the exemption. Following the receipt of information to rebut the EPA's preliminary decision and any subsequent hearing, the Agency will render a final decision on whether to terminate the exemption, taking into account information submitted to rebut the EPA's preliminary decision and information presented at any hearing, as applicable.

If you receive the EPA's preliminary decision to terminate the exemption and do not submit information to rebut that preliminary decision or request a hearing, or if you receive the Agency's final decision to terminate the exemption following the submission of information to rebut that preliminary decision or a hearing, you must resubmit a response in accordance with one of the options described in **Unit IV.B** of this Order within 30 calendar days of receipt of the EPA's decision to terminate the exemption, including as applicable the information required under **Unit V** of this Order. Failure to timely resubmit the response will constitute a violation of this Order and of TSCA section 15(1). Should the Agency terminate the exemption, a draft study plan will be due 30 days from the termination, with the final study plan being due 60 days from the termination.

If the EPA extinguishes a testing obligation pursuant to **Unit IV.B.2** of this Order, the corresponding exemption will be extinguished, as the exemption will no longer be necessary. In such a situation, companies who requested an exemption from that specific testing obligation are not required to reimburse the company that submitted existing data.

As explained in **Appendix B** on Cost Sharing, persons who receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Normally, this is worked out by the parties involved, without the involvement of the EPA. However, if agreement cannot be reached on the amount or method of reimbursement, and the company who is entitled to reimbursement requests in accordance with the procedures in **Appendix B** that the Agency order reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement. See TSCA section 4(c).

Option 4: Claim that You Are Not Subject to this Order

You may claim that you are not subject to this Order if you do not manufacture or process the chemical(s) identified by this Order; do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order.

An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your response in the CDX portal so that the EPA can evaluate the claim.

Note that if your company ceased manufacturing (including import) or processing of the chemical substance(s) subject to this Order more than five years prior to the effective date of this Order, you can claim that you are not subject to this Order.

In the instance that you claim you are Not Subject to this Order, your claim must include (1) a statement explaining why your company is not subject to this Order, such as no longer importing, manufacturing

or processing the subject chemical substance (intentionally or unintentionally) within the five years prior to the effective date of this Order, and not intending to manufacture (including import) or process the chemical within the period of testing provided by this Order (see **Unit V**), and (2) the certifying statement "I certify that the statements made in this letter are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law."

If based on the evidence you provide and other evidence available to the EPA, the Agency deems your claim to be inadequately substantiated, the EPA will deny your claim, and the original requirements and deadlines in this Order will remain. If your claim is approved, the Agency will notify you that you are not subject to this Order through CDX correspondence. The EPA expects to provide such notification within 45 days of the effective date of this Order.

To select this option, you must do so within 45 days of the effective date of this Order.

V. OVERVIEW OF TESTING REQUIRED BY THIS ORDER

This unit applies to Option 1: Develop the Information and Option 2: Submit Existing Information (**Units IV.B.1** and **IV.B.2**).

Where the required protocol is an EPA guideline, the guideline is available on the EPA website at http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances[4] and from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-605-6000). This EPA website also provides information on OECD guidelines, which are also available via OECD's website at https://www.oecd.org/chemicalsafety/testing[5]. **Appendix E** provides additional sources for guidelines associated with specific testing.

The EPA reserves the right to revise this Order to extinguish specific testing obligations where existing information subsequently comes to the Agency's attention that in the EPA's scientific judgment obviates the need for specific test data required under this Order. Specific information for ordered test(s) are provided in **Appendix E**.

See **Appendix E** for details on the required test protocols.

Table 3. Entities Responsible and Deadlines for Required Testing Protocol(s)/Methodology(ies)
Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday.

Test Names	Protocols Methodologies	Entities Responsible for Testing	Deadlines to Submit Final Reports to EPA
Environmental Hazard			
Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)	OECD 222 (2016)	Manufacturers	215 days after effective date of the Order
Avian Reproduction Test	OCSPP 850.2300	Manufacturers	295 days after effective date of the Order

[4] http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances
[5] https://www.oecd.org/chemicalsafety/testing

VI. REQUIREMENTS OF RESPONSE OPTION 1: DEVELOP THE INFORMATION REQUIRED BY THIS ORDER

A. OVERVIEW

The draft study plan is due to the EPA **80 days** after the effective date of this Order. The EPA will then review the draft study plan and provide input to ensure adequacy of the final study plan. For the final study plans and the final test reports, see the Deadlines for Responses, Study Plans, and Test Reports table in **Unit III.A**.

All testing described in **Unit V** must be conducted in accordance with the Good Laboratory Practice (GLP) standards in 40 CFR part 792, as specified in the CFR on the Effective Date of this Order. You must provide a statement of compliance with these GLP standards when submitting information to the EPA pursuant to this Order.

Deviations from the test guideline or specific GLP standards are allowed provided justifications for such deviations are approved by the EPA. A justification is required for each deviation. Justifications should demonstrate that, despite the deviation from the given test guideline or GLP standard, that data integrity, control of bias, and study quality will be maintained with similar effectiveness. Any requested deviations and corresponding justifications must be included in the draft study plan for the Agency's consideration and, if approved, described in the test report.

Once the EPA has completed its review of the submitted test reports and accepts the information as fully complying with your testing obligations under this Order, the Agency will notify you.

B. DRAFT STUDY PLAN REQUIREMENTS

1. Study Plan Requirements for All Categories of Tests

If you choose to develop the required information to comply with this Order, you must obtain and review the required protocols/methodologies. **Unit V** and **Appendix E** provide the protocols/methodologies that must be followed to perform each required test.

If questions and/or issues arise during Study Plan development, the EPA encourages questions/comments be submitted along with the Study Plan submission in accordance with the draft study plan deadline. If the Agency's review of the draft study plan that includes the questions/comments is delayed, the procedure outlined in **Unit III.B** will be followed for automatic extensions of the study plan.

In addition to requirements provided in **Appendix E** for a given test required by this Order, the Study Plans must contain the following information:

1. This Order number, excluding the unique 6-digit company number using X's in place of the unique company number so as to protect each company's private access to the reporting module via Central Data Exchange (CDX). For example, if your Order number is TO-2020-0000-438435-00-0 then provide this number in the Study Plan: TO-2020-0000-XXXXXX-00-0.

2. Name of test to be covered by the test protocol/methodology.

3. The name/number of the protocol/methodology identified in this Order which you intend to follow, a copy of the identified protocol/methodology with your proposed modifications, or a copy of the alternate protocol/methodology you propose to use. Justification(s) must be provided for any deviation from the protocol/methodology provided in this Order.

4. The identity of and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. A Certificate of Analysis of the test substance must be provided.

5. The sampling and analytical method that will be used.

6. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.

7. A description of all quality assurance and quality control protocols used.

8. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.

9. The name(s), mailing address(es), phone number(s), and e-mail address(es) of the appropriate individual(s) for the EPA to contact concerning the planned test.

10. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.

2. Modifying a Required Protocol/Methodology in a Draft Study Plan

The draft study plan must include the required protocols/methodologies outlined in **Unit VI.A.1** and **Appendix E**. If you believe modifications of these required protocols/methodologies are necessary, you should propose the modification in the draft study plan and submit to the EPA with request for the Agency to consider the modifications. Any consultation regarding modifications to the required protocols/methodologies will not extend the deadline for submission of the draft study plan.

Any submitted requests for modifications of the required protocols/methodologies must include a detailed description of the proposed modification as well as a detailed description of the justification and reasoning for such modifications. Requests for modifications of protocol/methodology or the use of an alternate protocol/methodology must discuss why such changes are appropriate and whether they could alter the validity of the study. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant section of the study plan describing the protocols/methodologies.

If the EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before the EPA will approve your study plan. The Agency has 15 days from the deadline for the study

plan to respond. For each day following this period that the EPA does not respond, the Agency will extend the deadline for the final study plan by one day (see **Unit III**).

3. EPA Review of Study Plans and Final Test Report

The EPA will not conduct a substantive review of any draft study plan that does not meet the requirements as provided in **Unit IV.B.1** and **Appendix E**. Such a submission does not constitute meeting the deadline for the draft study plan submission. **Unit III** provides information on deadlines and the EPA response timelines.

Failure to submit a draft study plan, final study plan, and final test report which do not fully comply with the terms of this Order and by the deadlines provided in **Unit III** may result in a violation of TSCA section 15.

a. Study Plans

Following review of a draft study plan submission, the EPA will indicate what modifications, if any, are required and must be incorporated into the final study plan. Accompanying a proposed final study plan submission, the submitter must provide a clean and red-lined version. The red-lined version will indicate the changes incorporated into the final study plan as compared with the draft study plan submission.

If the EPA requires modifications to a submitted draft study plan, the Agency may elect to provide a line-by-line list of comments that must be addressed and corrected before a final study plan will be approved. If the submitter receives a line-by-line list of comments, the submitter must address each individual comment and include this in their response to the Agency along with the proposed final study plan.

Prior to initiating any test, the Company/Consortium must first address the EPA's input on the study plan and receive the Agency's acceptance of the final study plan.

The EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under this Order.

If, after the final study plan has been approved or after testing is underway, you wish to make a modification to an identified protocol/methodology or use a different protocol/methodology, you must submit a request to the EPA to make these changes in your study and you must still meet the deadlines set out in **Unit V** and **Appendix E** for the relevant test or request an extension (see also **Unit III.C**), if needed.

Note that submitting questions to the EPA regarding study plan requirements will not extend the deadline for a study plan submission.

b. Final Test Reports

Once the EPA has completed its initial review and accepted data for all test reports subject to this Order for a given testing requirement, the Agency will notify the designated contact for the company or consortium subject to this Order that this testing requirement has been satisfied, which in turn will close out the testing requirement of this Order for the companies and participants in any consortium subject to

this Order. Failure to file a final test report meeting all the requirements in this Order by the deadline in **Unit III** is a violation of TSCA. Your final test report must be submitted along with the data in the associated Organisation for Economic Co-operation and Development (OECD) harmonized template format, if available. OECD harmonized templates can be located at https://www.oecd.org/ehs/templates/harmonised-templates.htm[6]:

Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222 (2016)

- Harmonized Template Identifier: 50-1

Avian Reproduction Test (OCSPP 850.2300)

- Harmonized Template Identifier: 53

VII. FEES FOR SUBMITTING INFORMATION

Per 40 CFR § 700.45, and taking into account the inflation adjustment that went into effect on January 1, 2022, the Test Order fee is $11,650 to be split evenly among the manufacturers who are required to test a chemical substance or mixture subject to the Test Order (accounting for small business considerations). Processors are not subject to this fee, nor are manufacturers who submit existing information or receive an exemption in compliance with this Order.

Small businesses may be subject to no more than 20% of the amount of the applicable fee. A company may qualify for a "small business concern" discount if their total number of employees is at or below the maximum allowed in the final rule for that company's North American Industry Classification System (NAICS) code (see 40 CFR 700.43). In order for an entity to qualify as a "small business concern," its number of employees shall not exceed the size standard for the applicable industry. When calculating the number of employees, the company must include the employees of all parent and subsidiary companies within the corporate chain. Please note that small business fees are only applicable to qualifying small businesses who are either not associated with a consortium or associated with an all-small business consortium. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses[7].

A company can identify itself as a small business when responding to this Order via the CDX application. The "small business concern" discount will be included in the determination of company-specific invoices for the distribution of the $11,650 fee across all manufacturers conducting testing for the given Test Order. Where a consortium is responsible for the fee for its members for purposes of this Order, and at least one of the members is not a small business, the EPA does not apply a "small business concern" discount to the portion of the $11,650 distributed to the consortium.

Fees for Test Orders under TSCA section 4 will be invoiced electronically by the EPA. Invoice notices will be populated into the specific user's "Copy of Record" screen in CDX and will contain a button that will initiate the payment process. When an invoice is generated, notification e-mails will be sent to the user's CDX inbox and the e-mail address associated with the relevant CDX account. Payment information will be collected in CDX and then submitted to Pay.gov for processing.

[6] *https://www.oecd.org/ehs/templates/harmonised-templates.htm*
[7] *https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses*

Note that there are many fees associated with TSCA-related activities. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-table[8]. The TSCA section 4 Test Order fee is separate from these fees. A company's inclusion in or exclusion from other TSCA fees is unrelated to that company's status with regards to TSCA section 4 Test Order fees.

Pursuant to 40 CFR § 700.45, the applicable fee shall be paid in full no later than 120 days after the effective date of the Order. Should the EPA invoice the fee more than 90 days after the effective date of the Order, payment will be due within 30 days of such invoicing.

VIII. INSTRUCTIONS IF YOU CHOOSE TO PARTICIPATE IN A CONSORTIUM

If you choose to form or join a consortium to share in the cost of developing the required information, you (as well as the other Order recipients who are participants in the consortium) must, individually in the CDX portal, state your intention to participate in a testing consortium for each specific chemical and specific test. Consortium participants must individually respond in the CDX portal with their intent to participate before designated leads are able to add them to the consortium.

In addition, the designated lead for the consortium must submit a consortium response to the EPA in the CDX portal. The response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by indicating each specific test. The response must also include contact information for the designated lead of the consortium, who must be domiciled in the United States. The designated lead for the consortium must submit the response and required information on behalf of the consortium and its member companies by the deadlines listed in **Unit III.A**. Submissions made on behalf of the consortium must be in accordance with instructions in **Appendix C**. Note that a consortium lead need not be a recipient of an Order; other entities (such as trade organizations) may act as a lead and submit the information required under this Order. After the results of the last required test of this Order are submitted and the EPA accepts the information as complying with this Order, or the Agency accepts existing information submitted by the Consortium, the EPA will provide notification of compliance with this Order to this Order's recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with this Order (with the study plan and results being submitted by the consortium) and is individually liable in the event of any failure to comply with this Order. If the consortium fails to submit the information or meet any of the requirements of this Order on your behalf, you will be in violation of this Order unless you submit the required information or meet the requirement individually.

The Agency has provided a list of the manufacturers and processors that have received this Order at the top of this Order in the Summary Information section. This list of manufacturers and processors can be used to help Order Recipients form a consortium to jointly develop information, consolidate testing and share the cost of testing. Information on cost sharing is provided in **Appendix B**.

IX. CONFIDENTIALITY

Under TSCA section 14(b)(2), health and safety studies submitted under TSCA and data reported to or otherwise obtained by the Administrator from health and safety studies are not protected from disclosure if the studies and data concern a chemical that is offered for commercial distribution, or for which

[8] *https://www.epa.gov/tsca-fees/tsca-fees-table*

testing is required under TSCA section 4 or notification is required under TSCA section 5. However, TSCA section 14(b)(2) does not apply to information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised of the chemical subject to this Order. Therefore, some or all of the information in the studies required to be submitted under this Order might not be eligible for TSCA confidential business information (CBI) protections.

Information submitted under TSCA that you wish to have the EPA protect as CBI must be clearly identified as such when submitted. For sections of the report that are claimed as CBI, the report must be accompanied by a sanitized version of the report only removing the specific information claimed as CBI. A sanitized test report that redacts all or most of the study may be rejected by the Agency as not satisfying the requirements of this Order.

When claiming information as CBI, you must certify to the following:

"I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001."

In addition, information claimed as CBI must be substantiated upon submission, with the exception of information described in TSCA section 14(c)(2). Guidance for substantiating CBI claims may be found at https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations.

Failure to follow the statutory requirements for asserting and substantiating a CBI claim may result in the information being made available to the public without further notice to the submitter.

When a claim of CBI under TSCA section 14 is approved by the EPA, the Administrator will generally protect that information from disclosure for 10 years (unless the protection from disclosure is withdrawn by the person that asserted the claim), whereupon the claim must be reasserted and re-substantiated if the submitter wishes to maintain the CBI claim. In certain cases, the Agency may review claims prior to the expiration of the 10-year period.

Under circumstances stated in TSCA section 14(d), the EPA may disclose information claimed as CBI to other persons including, for example, Federal and State authorities, health and environmental professionals, poison control centers, and emergency responders.

X. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS ORDER

Failure to comply with any of the requirements in this Order is a violation of TSCA section 15 and could subject you to civil and/or criminal penalties under TSCA section 16, 15 U.S.C. § 2615 as modified by the Federal Civil Penalties Inflation Adjustment Act. Each day that failure to meet the requirements continues constitutes a separate violation.

XI. REFERENCES

The following is a listing of the documents that are generally applicable to this Order. **Appendix E** provides references specific to certain testing requirements in this Order. Please note that references, guidance, and information from additional sources could be considered, with EPA approval, during the development of study plans.

The docket includes these documents and other information considered by the EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

General References for this Test Order

1. U.S. EPA (2021). 1,1,2-Trichloroethane Test Order [EPA-HQ-OPPT-2018-0421]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane[9]

2. U.S. EPA (2020a). Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane [EPA-740-R-20-003]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf[10]

3. U.S. EPA (2020b). Use Report for 1,1,2-Trichloroethane (CASRN 79-00-5) [EPA-HQ-OPPT-2018-042]. Washington DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT). https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0421-0018[11]

Earthworm Reproduction (*Eisenia fetida/Eisenia andrei*) Test References

[9] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane*
[10] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf*
[11] *https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0421-0018*

4. OECD. (2016). Test No. 222: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*). Paris, France: OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing. https://doi.org/10.1787/9789264264496-en[12]

Avian Reproduction Test References

5. Elovaara, E., Hemminki, K., Vainio, H. (1979). Effects of Methylene Chloride, Trichloroethane, Trichloroethylene, Tetrachloroethylene and Toluene on the Development of Chick Embryos. Toxicology, Volume 12, Issue 2, Pages 111-119, ISSN 0300-483X. https://doi.org/10.1016/0300-483X(79)90037-4[13]

6. U.S. EPA (2012). OCSPP 850.2300: Avian Reproduction Test [EPA 712C-023]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012[14]

7. U.S. EPA (2020). Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis. Washington DC: U.S. Environmental Protection Agency, Office of Pesticide Programs (OPP). https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf[15]

8. U.S. Geological Survey (USGS). (1991). USGS Monitoring Data: National Water Quality Monitoring Council [Database] – Air, Groundwater, Sediment, Soil, Surface Water, Tissue. http://www.waterqualitydata.us/portal/[16]

XII. PAPERWORK REDUCTION ACT NOTICE

This collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. (OMB Control No. 2070-0033). Responses to this collection of information are mandatory under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 137 hours for the average response on a per-chemical basis. Under the PRA, burden is defined at 5 CFR 1320.3(b). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

XIII. FOR FURTHER INFORMATION CONTACT

For technical information contact: TSCATestOrders@epa.gov.

[12] *https://doi.org/10.1787/9789264264496-en*
[13] *https://doi.org/10.1016/0300-483X(79)90037-4*
[14] *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012*
[15] *https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf*
[16] *http://www.waterqualitydata.us/portal/*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

XIV. SIGNATURE

Under the authority in TSCA section 4(a)(2), the United States Environmental Protection Agency hereby issues this Order to take effect on the date of my signature.

MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF Date: 2022.03.24 06:46:32 -04'00'

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Enclosures

APPENDIX A - EQUIVALENCE DATA

For purposes of this Order, "equivalence data" means "chemical data or biological test data intended to show that two substances or mixtures are equivalent." Also, when a chemical substance is "equivalent," it means "that a chemical substance is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance," as defined in 40 CFR § 790.3.

If testing under TSCA section 4(a) is required of an equivalent chemical substance, the EPA may grant an exemption from testing to the manufacturer or processor of one substance if the information required under TSCA section 4(a) is submitted or is being developed on the other, and the manufacturer or processor submits the following information to support equivalence with its exemption application:

1. The chemical identity of each chemical substance or mixture manufactured or processed by the applicant for which the exemption is sought. The exact type of identifying data required may be specified in this Order and may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

2. The basis for the applicant's belief that the substance or mixture for which the exemption is sought is equivalent to the test substance or mixture.

3. Any other data which exemption applicants are directed to submit in this Order which may have bearing on a determination of equivalence. This may include a description of the process by which each chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

APPENDIX B - COST SHARING

The EPA encourages Order recipients that are responsible for developing the same information on the same chemical(s) to avoid duplicative testing and share the cost of information development. If a test is conducted according to a final, approved protocol, it is sufficient that the test is conducted once. Two ways to avoid duplicative testing are discussed in this Order. They are forming or joining a consortium, discussed in **Unit VIII**, or requesting an exemption, discussed in **Unit IV.B.3**.

Consortia

Persons that form or join a consortium typically execute an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate.

Exemptions

Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the testing and submit the required information that is the basis for the exemption for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is ideally negotiated between the companies involved, without the EPA's participation. The Agency has promulgated regulations that explain how the EPA views fair and equitable reimbursement in the context of TSCA section 4(a) test rules. In general, those regulations (40 CFR § 791.40 through § 791.52) make a presumption that a person's fair share of the test costs is in proportion to their share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations do not apply to TSCA section 4 orders, you may wish to consider them as you decide how to share the costs.

If persons subject to an order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the person whose information is the basis for the exemption may request that the Administrator order the person(s) granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA section 4(c)(3)(A). Upon receipt of such a request, the EPA will determine fair and equitable reimbursement and issue an order accordingly. The Agency may, at its discretion, make use of procedures and standards applicable to data reimbursement regarding TSCA section 4 rules, contained in 40 CFR part 791.

APPENDIX C - HOW TO ACCESS THE CDX APPLICATION AND RECORDKEEPING REQUIREMENTS

How to Access the CDX Application

The initial response, draft and final study plans, final test reports with underlying data, existing studies, any testing related requests, and all related correspondence must be submitted electronically to the EPA as follows:

1. Submit to the EPA's CDX system. CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for submissions to the Agency.

2. The URL for the CDX website is *https://cdx.epa.gov/*[17] which takes you to the CDX homepage.

3. On the homepage you may select "Log in" or, if you haven't already registered, select "Register with CDX."

4. Once you have logged on to CDX, follow the instructions for submitting TSCA section 4 order information. To access the instructions, select "Report electronically" on the EPA Internet homepage at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*[18].

5. The CDX Help Desk is available for data submission technical support between the hours of 8:00 am and 6:00 pm (EST) at 1-888-890-1995 or helpdesk@epacdx.net. The CDX Help Desk can also be reached at 970-494-5500 for international callers.

The EPA may revise these submission instructions with advance notice.

Recordkeeping

You must retain copies of all information documenting your compliance with this Order for ten years. This includes your response and other documents and correspondence submitted to comply with this Order, such as test protocols, testing related requests, final test reports with their underlying data, and any penalties remitted.

[17] *https://cdx.epa.gov/*
[18] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*

APPENDIX D - ORDER RECIPIENT SELECTION

This Appendix describes the process by which the EPA identified recipients of this Order. This information is for your use, and does not govern the obligations under this Order or the identities of the companies subject to this Order. A recipient of this Order that manufactures or processes the chemical as per the definitions provided in **Unit I.B** is subject to this Order, regardless of the basis on which the Agency identified the recipient.

The manufacturers and processors of the chemical subject to this Order were determined in the following manner:

The EPA included in this Order as recipients all companies comprising the final list of manufacturers subject to fee payments[19] for *p*-dichlorobenzene developed under the "Fees for Administration of Toxic Substances Control Act" rule in 2020, as well as, manufacturers identified by other sources, including Toxics Release Inventory[20] (TRI) reporting from 2016 to 2020 and Chemical Data Reporting (CDR) reporting from 2020. The Agency also included in this Order Companies who reported as "Processors" of this chemical to the 2016 to 2020 TRI. Although the EPA recognizes that there are processors who do not report to TRI, this database was used to identify processors for the purposes of this order because it is the Agency's most comprehensive source to establish a well-verified list of processing companies.

[19] *https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations*
[20] *https://www.epa.gov/toxics-release-inventory-tri-program*

APPENDIX E - SPECIFIC REQUIREMENTS AND GUIDANCE FOR THIS ORDER

This appendix provides requirements of study plans and test reports for specific testing requirements of this Order. Additionally, this appendix provides additional reference material(s) associated with the testing required in this Order.

For information on how the EPA determined the need for the testing requirements of this Order, refer to **Unit II.B.**

I. Environmental Hazard

a. Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222 (2016)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to OECD 222 include:

1. Final exposure concentrations must capture both lethal and sub-lethal effects over a period of 8-weeks, such that they bracket the Effective Concentration (ECx) estimate. To ensure these requirements are met, it is highly recommended that a range finding test is conducted before the initiation of the definitive test.

2. Soil must be mixed and homogenized with the chemical, and the source, purity, and a Certificate of Analysis of the test substance must be reported. The draft study plan will not be approved by the EPA without the purity of the test material.

3. The analytical laboratory must describe how they will conduct analytical verification of the test material at the beginning and end of the test, and every 7-days throughout the test duration.

4. A description must be provided as to whether the use of formulated/artificial or field-collected soil is being implemented (the EPA recommends formulated/artificial soil).

5. An outline must be provided of the raw data to be collected for each sub-lethal and lethal endpoint as well as statistical analyses that are planned.

6. Because 1,1,2-trichloroethane is a volatile substance, a description must be provided as to how the test laboratory will account for volatilization.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 215 days after effective date of the Order and must include the following, as applicable:

1. Harmonized Template ID: 50-1

2. Harmonized Template URL: https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm[21]

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. OECD (Organisation for Economic Co-operation and Development). (2016). Test No. 222: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*). Paris, France: OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing. https://doi.org/10.1787/9789264264496-en[22]

b. Avian Reproduction Test (OCSPP 850.2300)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to OCSPP 850.2300 include:

1. An outline must be provided of the raw data to be collected for each sub-lethal and lethal endpoint as well as statistical analyses that are planned.

2. The study laboratory must describe how they will conduct analytical verification of the test material in the diet at the beginning, middle and end of the test to ensure exposure, and the source, purity, and a Certificate of Analysis of the test substance must be reported. The draft study plan will not be approved by the EPA without the purity of the test material.

3. A description should be provided as to how frequently the test diets will be mixed, to ensure for volatile substance that the concentrations are not reduced from initial concentrations by more than 20%.

4. The Northern bobwhite (*Colinus virginianus*) must be used instead of the mallard (*Anas platyrhynchos*) or other test species recommended in the guideline, because it is less prone to regurgitation and easier to measure food consumption for this species.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 295 days after effective date of the Order and must include the following, as applicable:

1. Harmonized Template ID: 53

2. Harmonized Template URL: https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm[23]

[21] *https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm*
[22] *https://doi.org/10.1787/9789264264496-en*
[23] *https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm*

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. Elovaara, E., Hemminki, K., Vainio, H. (1979). Effects of Methylene Chloride, Trichloroethane, Trichloroethylene, Tetrachloroethylene and Toluene on the Development of Chick Embryos. Toxicology, Volume 12, Issue 2, Pages 111-119, ISSN 0300-483X. https://doi.org/10.1016/0300-483X(79)90037-4[24]

2. U.S. EPA (2012). OCSPP 850.2300: Avian Reproduction Test [EPA 712C-023]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012[25]

3. U.S. EPA (2020). Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis. Washington DC: U.S. Environmental Protection Agency, Office of Pesticide Programs (OPP). https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf[26]

4. USGS. (1991). USGS Monitoring Data: National Water Quality Monitoring Council [Database] – Air, Groundwater, Sediment, Soil, Surface Water, Tissue. http://www.waterqualitydata.us/portal/[27]

[24] *https://doi.org/10.1016/0300-483X(79)90037-4*
[25] *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012*
[26] *https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf*
[27] *http://www.waterqualitydata.us/portal/*

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

VINYL INSTITUTE, INC., Petitioner, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	)	Case No. 22-1089

PETITIONER'S MOTION FOR LEAVE TO MAKE ADDITIONAL SUBMISSIONS TO THE RECORD PURSUANT TO SECTION 19(b) OF THE TOXIC SUBSTANCES CONTROL ACT

Pursuant to Section 19(b) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2618(b), Petitioner Vinyl Institute, Inc. (VI) hereby motions for leave to make additional submissions to the administrative record for the *Order Under Section 4(a)(2) of the Toxic Substances Control Act* (Mar. 24, 2022) (Test Order) (attached as Ex. A) issued by Respondent U.S. Environmental Protection Agency (EPA). EPA issued the Test Order with no opportunity for public review and comment, therefore necessitating an order by this Court allowing the VI to supplement the record with additional comments, as well as material information and data, all of which will substantially facilitate any further judicial review in this matter. In support of this motion, the VI submits the following:

BACKGROUND

I. Procedural History

On March 24, 2022, EPA issued the Test Order requiring that certain companies conduct studies on the chemical substance 1,1,2-trichloroethane, which EPA maintains are necessary to assess potential risks to the environment. *See* 15 U.S.C. § 2603(a)(2); Ex. A at 2. The Test Order requires the companies to conduct two studies assessing ecotoxicity: an earthworm reproduction test and an avian reproduction test. Ex. A at 6. This is not the first time EPA has required these companies to conduct testing on 1,1,2-trichloroethane. EPA previously issued a test order in January 2021 requiring ecotoxicity testing on aquatic organisms, dermal absorption testing, and worker inhalation and dermal exposure studies.[1] *Id.* at 5.

Only the avian reproduction test is at issue in this motion.[2] A final report detailing the results of the avian testing is due 295 days after the effective date of the Test Order (or January 18, 2023), subject to automatic extensions if EPA fails to meet certain deadlines. Ex. A at 9-10, 14. On May 23, 2022, the VI filed a

[1] Collectively, the cost of completing all of the studies required by the two test orders could reach upward of $1 million. The avian reproduction study standing alone will, at a minimum, cost at least $200,000. As such, it imperative that EPA adequately justify the need for each test order.

[2] The Test Order requires that the reproductive study be carried out on Bobwhite quail, a ground-dwelling bird native to the United States. Ex. A at 29.

Petition for Review (Doc. #1947770) pursuant to TSCA Section 19(a), 15 U.S.C. § 2618(a), seeking review of the Test Order.[3]

The Test Order states the avian study will provide information necessary for EPA to perform its TSCA section 6(b) risk evaluation of 1,1,2-trichloroethane. Ex. A at 2; 15 U.S.C. § 2605(b). Section 6(b) tasks EPA with determining whether a chemical substance presents an unreasonable risk of injury to health or the environment. Here, EPA initiated a section 6(b) risk evaluation after it designated 1,1,2-trichloroethane as a High-Priority Substance following the TSCA section 6(b) prioritization process. *High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability*, 84 Fed. Reg. 71,924 (Dec. 30, 2019).

If, based on the risk evaluation, EPA determines that 1,1,2-trichloroethane presents an unreasonable risk for one or more uses of the chemical substance, it will then propose and issue a risk management rule under TSCA section 6(a) prohibiting or otherwise restricting its manufacture, processing, distribution, use, and/or disposal. 15 U.S.C. § 2605(a).

[3] The Test Order originally applied to seven companies, with the VI managing the consortium of companies conducting the required testing. On August 5, 2022, EPA modified the Test Order by removing two companies.

II. EPA Must Satisfy Specific Statutory Requirements Before Issuing A Test Order Under TSCA Section 4

EPA must meet certain prerequisites and make particular evidentiary showings before it may issue a test order. TSCA section 4(a)(2)(A)(i) authorizes EPA to, by rule, order, or consent agreement, "require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary…to perform a risk evaluation under section 2605(b) of this title." 15 U.S.C. § 2603(a)(2)(A)(i). To exercise this authority, EPA must provide a Statement of Need justifying that a test order is necessary. 15 U.S.C. § 2603(a)(3). Specifically, EPA must: (i) "identify the need for the new information"; (ii) "describe how information reasonably available to the Administrator was used to inform the decision to require new information"; (iii) "explain the basis for any decision that requires the use of vertebrate animals"; and (iv) "explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement." *Id.*

Significantly, TSCA places a high priority on minimizing animal testing. The statute mandates that EPA reduce and replace the use of vertebrate animal testing whenever practicable and scientifically justified. 15 U.S.C. § 2603(h)(1).[4]

[4] EPA must also promote the development of non-animal testing methods, as well as group similar chemicals for testing and allow companies to operate through consortia to reduce duplicative animal tests. 15 U.S.C. § 2603(h)(1)-(2).

Before issuing a test order, EPA must consider reasonably available alternatives, such as existing toxicity information, computational toxicology, bioinformatics, and high-throughput screening methods and the prediction models of those methods. 15 U.S.C. § 2603(h)(1)(A)(i)-(iii).[5]

Moreover, because of the significant resource and financial burdens associated with test orders, TSCA section 4 obligates EPA to reduce testing burdens through the use of screening tests (e.g., NAMs) before requiring more robust studies. EPA "shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary." 15 U.S.C. § 2603(a)(4). EPA may proceed to more advanced testing only when information available to the EPA justifies not first requiring companies to carryout screening-level testing. *Id.*

Furthermore, highlighting the importance of a complete administrative record, any EPA decision made under section 4 must be based on the weight of the scientific evidence. 15 U.S.C. § 2625(i). Thus, section 4 does not allow EPA to determine the need for a test order based on only a cursory review of available evidence or on an incomplete administrative record. Indeed, TSCA explicitly

[5] Alternatives such as computational toxicology and informatics tools are referred to as "new approach methodologies" or "NAMs." Ex. A at 8.

authorizes this Court pursuant to section 19(b) to allow stakeholders to supplement the administrative record with any missing relevant data and analysis.

Finally, EPA does not have absolute discretion to issue a test order, as it did here, thus bypassing any public notice or comment. Rather, section 4 provides EPA with three options for imposing a testing requirement on companies: a test rule, a test order, or a testing consent agreement. But when EPA elects to use a test order – the one option that does not allow for any stakeholder notice or input before finalization – EPA must explain in the Statement of Need why a test order is warranted over the other two options. 15 U.S.C. § 2603(a)(3).

III. The Test Order and EPA's Statement of Need

The Test Order's Statement of Need *briefly* addressed: (i) the identification of other chemical substances (or "analogues") that might provide relevant toxicity data where information on 1,1,2-trichloroethane is limited; (ii) whether avian species are sufficiently exposed to 1,1,2-trichloroethane in the environment so as to justify additional testing; (iii) whether there are alternative methods (e.g., NAMs) that could support a tiered testing approach or obviate the need for vertebrate animal testing; and (iv) why EPA proceeded via a test order, with no public notice or comment, rather than a rulemaking or consent agreement. Ex. A at 5-9.

Analogs and Existing Toxicity Data: EPA stated that it searched for information on 1,1,2-trichloroethane in peer-reviewed literature databases, gray

literature (technical reports, reference books, dissertations), and information submitted to EPA during the prioritization process and under other TSCA programs. Ex. A at 6-7. In addition, the Test Order indicated that EPA reviewed "existing measured environmental hazard data for aquatic and terrestrial species for 1,1,2-trichloroethane and the identified analogues from the EPA's ECOTOX Knowledgebase (ECOTOX) and information submitted under TSCA, (e.g., under Sections 4 and 8(e)), [the Federal Insecticide, Fungicide, and Rodenticide Act], and the Endocrine Disruptor Screening Program (EDSP)." *Id.* at 7. The Test Order was not clear whether EPA's searches on the chemical analogues included peer-reviewed literature databases and gray literature.

Chemical analogues provide relevant data and information on hazards that can be used to fill data gaps for the primary chemical substance. Ex. A at 8. The Test Order identified seven substances as chemical analogues of 1,1,2-trichloroethane: 1,1,1-trichloroethane (with Chemical Abstracts Service Registry Number (CASRN) 71-55-6), trichloroethane (CASRN 25323-89-1), 1,2,3-trichloropropane (CASRN 96-18-4), 1,2,3,4-tetrachlorobuta-1,3-diene (CASRN 1637-31-6), 1,1,5,5-tetrachloropentane (CASRN 17655-64-0), 1,1,2,3-tetrachloropropane (CASRN 18495-30-2), and 1,2,3,4-tetrachlorobutane (CASRN 3405-32-1). *Id.* Per the Test Order, EPA relied solely on its Analog Identification Methodology (AIM) software to identify chemical analogues for 1,1,2-

trichloroethane. *Id.* at 7-8. EPA, however, did not incorporate other available and oft-used EPA tools to identify additional analogues and ensure that it had considered a full list of chemical substances similar in structure to 1,1,2-trichloroethane and any associated toxicity studies.

Instead, regarding existing toxicity information, the Test Order stated that "[n]o avian toxicity data following chronic exposures were identified for 1,1,2-trichlorethane or identified analogues for any endpoint." Ex. A at 8. According to EPA, it therefore needs to fill this data gap because "[w]ithout toxicity data, the EPA is unable to determine if chronic exposures to 1,1,2-trichlorethane pose a risk to terrestrial vertebrates." *Id*. While the Test Order generally indicated that there is acute exposure data for birds covering 1,1,2-trichloroethane and one other listed analogue, it did not specifically identify any studies or discuss why such data could not be used as part of a tiered testing approach. *Id.* (Table 1).

The only other toxicity data cited by EPA came from a 1979 study that "qualitatively indicates exposure to 1,1,2-trichloroethane caused developmental toxicity to chick embryos," but with EPA admitting that "the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure." Ex. A at 9 (citing Elovaara, *et al.*, 1979). Nevertheless, the Test Order concluded that "the [study's] evidence of

teratogenicity in chick embryos indicates that additional data are needed to understand the potential effect following chronic dietary exposure." *Id.*

Environmental Exposure Data: EPA cited to a single source of monitoring data, the U.S. Geological Survey (USGS) Water Quality Portal (WQP) database, and only stated that 1,1,2-trichloroethane has been detected "in media to which terrestrial vertebrates could be exposed, including groundwater, sediment, soil, surface water, and biota." Ex. A at 9. The Test Order, however, did not quantify the presence of 1,1,2-trichloroethane currently in environmental media, pinpoint any specific monitoring data points finding 1,1,2-trichloroethane in environmental media, or otherwise explain how this data indicate that avian species are being exposed to 1,1,2-trichloroethane at levels of concern.

Tiered Testing And Alternatives To Animal Testing: Regarding alternative methods such as computational toxicology or high-throughput screening, the Test Order simply stated that "[n]o approved or readily available new approach methodologies (NAMS) were identified that could be used to inform the data gap for avian toxicity following chronic exposure." Ex. A at 8. The Test Order did not explain how EPA made this determination, what NAMs EPA evaluated and why they were ruled out, or whether the Agency considered alternative methods targeted to other toxicological endpoints or other species.

Need For Order As Opposed To A Rule Or Consent Decree: The Test Order stated that, to meet regulatory timetables, an order "will allow the Agency to target known manufacturer and processor recipients to obtain the needed information more quickly." Ex. A at 8. However, the Test Order did not indicate why EPA waited until March 2022 to issue the order, particularly as it was able to issue a prior test order covering other test data in January 2021, and did not otherwise consider the substantial risk that such a test order, issued with no public notice or opportunity to comment, might be based on something other than all available evidence or a complete administrative record.

IV. TSCA Section 19(b) Is Designed To Guard Against An Inadequate Statement of Need Or Incomplete Administrative Record

To ensure that a test order is based on a full scientific record and to otherwise facilitate judicial review, section 19(b) allows a petitioner to seek leave from the Court to submit additional comment, information, and data for inclusion in a test order's administrative record. The Court has authority to grant such a request if the additional submissions would be material and there are reasonable grounds for the petitioner's failure to submit the information and data during the administrative proceeding. If section 19(b)'s requirements are met, the Court may order EPA to re-open the administrative proceedings so that EPA can consider the newly submitted comments and materials, and decide whether to modify or set aside the test order. To the extent that EPA amends the test order and the

petitioner does not otherwise withdraw the petition for review, the Court would then review the new order. 15 U.S.C. § 2618(b).

ARGUMENT

TSCA section 19(b) allows a petitioner to apply to the court for leave to make additional comments and submissions to the record during judicial review, if such submissions would be material and the petitioner's failure to make these submissions during the Agency proceeding in question was reasonable.

Here, EPA issued the Test Order without public notice or opportunity for stakeholder input. In fact, before the Test Order was published, the companies subject to the Test Order were never consulted by EPA, or given the opportunity to submit additional evidence or assess the adequacy of EPA's decision to require avian reproduction testing. This holds true despite the formation and registration with EPA of a consortium (managed through the VI) for this chemical substance, which was encouraged by EPA to facilitate Agency communications with the affected companies. Thus, it is reasonable that the VI did not previously provide to EPA any submissions during the Test Order "proceeding."

Further, that these submissions would be material is illustrated by the threadbare and conclusory Statement of Need rationalizing EPA's Test Order. The Statement of Need, after being stripped of its discussion regarding procedural history and regulatory background, totals just several pages, largely consisting of

summary or conclusory statements. Indeed, an independent expert review of the Test Order and administrative record demonstrates that EPA omitted key analysis, information, and data, all of which indicate birds have limited or marginal exposure to 1,1,2-trichloroethane and that the substance poses, at most, minor toxicity concerns. Therefore, the Court should grant the VI's motion so the VI can submit additional information to the administrative record and EPA can reconsider the necessary scope of the Test Order.

I. Independent Third-Party Review Of The Test Order

The VI retained Cardno ChemRisk (now known as Stantec), a scientific consulting firm that specializes in characterizing environmental risk, to assess whether EPA followed section 4's requirements, and specifically whether EPA sufficiently identified a need for an avian reproduction study. Stantec's report is attached as Ex. B. Stantec not only reviewed the Test Order and the materials cited in the Certified Index produced by EPA (Doc. #1956004), but also conducted an independent review of publicly available studies regarding 1,1,2-trichloroethane and analogues discussed in the Test Order, utilized several EPA-approved tools to identify additional analogues not mentioned in the Test Order, reviewed publicly available environmental data for 1,1,2-trichloroethane, and investigated additional non-vertebrate tools that could have been used as a form of tiered testing to minimize required animal testing and otherwise reduce testing burdens.

As discussed below, Stantec's review concluded that relevant information and data not considered at all by EPA or, at a minimum, not specifically analyzed in the Statement of Need, could compel EPA to withdraw the Test Order completely or at least employ a more reasonable tiered testing approach. Accordingly, the VI should have an opportunity to make additional comments and submissions to the record so EPA may adequately determine what, if any, form of avian testing can be required under TSCA section 4.

II. Neither The Test Order Nor The Administrative Record Contain Any Analysis Of Environmental Data Showing 1,1,2-Trichloroethane Exposures To Birds Are Extremely Low

A test order must be "necessary" for EPA's performance of a section 6(b) risk evaluation. 15 U.S.C. § 2603(a)(2)(A)(i). Avian testing is unwarranted if birds are not exposed in the ambient environment to 1,1,2-trichloroethane sufficient to pose a risk. Ex. B at 11. Neither the Test Order nor administrative record, however, contained any analysis of this important factor. *Id*. EPA, in one sentence, merely cited to the USGS WQP database for the proposition that 1,1,2-tricholorethane has been found in various environmental media (ground water, surface water, sediment, soil, biota). *See* Ex. A at 9. What EPA did not do is discuss that data or acknowledge that: (i) 1,1,2-trichloroethane's detection frequency is virtually *de minimis* across all key environments; and (ii) the

concentration levels typically found would pose little risk to birds based on available evidence regarding toxicity.

Indeed, Stantec's comments would provide much needed analysis if included in the administrative record. Except for groundwater, to which birds would have little direct contact, the detection frequency for air, soil, sediment, surface waters, and subsurface waters over many decades ranged from 0%-1.2%. Ex. B at 11-14. As to surface waters, the most likely exposure route for birds, the detection frequency was just 0.8%. *Id.* at 14 (Table 14). For soils, it was 0.5%. *Id.* In air, 1,1,2-trichloroethane never exceeded the limit of detection.[6] *Id.*

A similar conclusion stems from the concentration levels detected in the environment. For instance, Stantec used an EPA computational tool (Web-ICE) to calculate the hazardous concentration (HD_5) level of 1,1,2-trichloroethane (21.79 mg/kg) that would be protective of 95% of exposed birds. Ex. B at 16-20. This concentration level, which is applicable to acute toxicity, was extrapolated in the model by using known toxicity levels for other species. *Id.* at 16-17. The HD_5 level calculated for 1,1,2-trichloroethane is several orders of magnitude higher than would result from environmental concentrations typically reported in the USGS

[6] Stantec also explained why a low detection frequency (3.0%) and concentration levels found in saltwater and freshwater fish, a dietary component for certain bird species, would also pose little risk to avian species, as 1,1,2-trichloroethane has a low potential for bioaccumulation in fish. *Id.* at 13.

WQP database. *Id.* at 19-20 (giving examples for surface waters).[7] In other words, it would be "improbable that birds would be exposed to levels in the environment that are sufficiently high to cause adverse effects."[8] *Id.* at 19.

Stantec also inferred based on the HD_5 for 1,1,2-trichloroethane that there is little risk of chronic toxicity to birds. Stantec noted that "[a]cute toxicity…can be used to inform potential chronic toxicity and is often used as a step in a tiered testing strategy to determine whether chronic testing is warranted." Ex. B at 16-17. For example, given a Bobwhite quail's average daily water ingestion, weight, and life span, the amount of 1,1,2-trichloroethane consumed via exposure to surface waters "over its lifetime would still be below the HD_5." *Id.* at 20 (i.e., even if a bird consumed water contaminated with 1,1,2-trichloroethane every day for its entire lifetime, with no metabolization or excretion of the substance, it would still not reach a dose predicted to cause toxicity); *see also id.* at 14 (Stantec concluding "the infrequent detection of 1,1,2-trichloroethane in environmental samples

[7] By way of example, given the maximum levels of 1,1,2-trichlorethane detected in streams and lakes, a Bobwhite quail would have to consume water in amounts orders of magnitude above their estimated daily ingestion rate to reach a level of concern for acute toxicity. *Id.* at 20.

[8] Similarly, Stantec cited to a recent report issued by the Agency for Toxic Substances and Disease Registry (ATSDR), a federal public health agency, containing environmental exposure data for air. The concentrations of hexachloroethane, an analogue of 1,1,2-trichloroethane, that produced adverse effects in birds via inhalation was approximately 5,000,000-fold higher than the maximum concentration of 1,1,2-trichloroethane reported by ASTDR. *Id.* at 11.

indicates that chronic exposure scenarios for birds are unlikely (i.e., birds are unlikely to have a continuous exposure to 1,1,2-trichloroethane because it is not regularly found in environmental media.")).

Not surprisingly, Stantec concluded these data as a whole "indicate that 1,1,2-trichloroethane is rarely detected in environmental samples, and if it is, the environmental concentrations would be well below the doses used in acute and chronic studies" – i.e., "the potential risk for these species is low." Ex. B at 11. As Stantec points out, this raises serious questions as to whether any avian testing should be required under section 4. *Id.* ("As exposure is a critical component for a chemical to represent a risk, the absence of 1,1,2-trichloroethane in most environmental samples suggests additional hazard testing for [the chemical] is not a critical data need."). This type of analysis, however, does not appear in the administrative record or the Test Order.

III. EPA Did Not Identify In The Test Order Or The Administrative Record A Complete List Of 1,1,2-Trichloroethane Analogues That Could Provide Relevant Toxicity Data

Even if additional data may be needed for 1,1,2-trichloroethane, the Test Order did not consider or even mention readily available toxicity data indicating that the chemical is not toxic to birds. For instance, it is common practice when assessing a chemical's toxicity to rely on existing data for "analogues" – chemicals with similar structures to the substance of interest – to fill-in any data gaps instead

of conducting new tests. Ex. B at 6.[9] In the Test Order, EPA used its Analog Identification Methodology (AIM) software to identify seven analogues. Ex. A at 7; Ex. B at 6. It then, in conclusory fashion, noted that one analogue, 1,1,1-trichloroethane, had associated with it some hazard data regarding acute exposure in birds, but the Test Order did not identify the underlying study(ies) or provide further analysis as to whether such data would be helpful in assessing environmental risk. Ex. A at 8 (Table 1).

To better inform the process, Stantec employed another EPA tool often used for the identification of structural analogues, the CompTox Chemicals Dashboard, which resulted in the identification of seven additional analogues for 1,1,2-trichloroethane not listed in the Test Order. Ex. B at 7-8 (Table 2). Nowhere in the Test Order or administrative record did EPA consider these other analogues and whether they could be leveraged to provide more information on avian toxicity. *Id.* at 8-9. The VI, therefore, should have the opportunity to supplement the record so that all relevant analogues are identified, evaluated, and used to inform any EPA decision to issue an order for avian testing.

[9] This process of using known information from one chemical to predict the same property in another, data-poor substance is known as "read-across." *Id.*

IV. EPA Did Not Include In The Administrative Record Data For Analogues Identified By Stantec Or Initially Listed By EPA Demonstrating The Low Toxicity Of 1,1,2-Tricholorethane

Based on an initial review of the analogues identified by Stantec and those listed by EPA, Stantec found at least one additional analogue that has avian subchronic data associated with it, and another analogue listed in the Test Order with three acute avian studies that were never considered by EPA. Ex. B at 8-9.

As to the analogue missed by EPA, Stantec located a repeated dose (subchronic) inhalation study for hexachloroethane that could help fill the purported data gap for 1,1,2-trichloroethane. The study, which involved Japanese quails being exposed to hexachloroethane vapor over a six week period, found virtually no toxicological impacts of concern (e.g., mortality, clinical signs, body weight changes, or gross tissue or organ changes). Ex. B at 9-10.

Stantec was then able to use this study and publicly available information to calculate the type of environmental hazard values sought in the avian study required by the Test Order, and concluded that the study "indicates that…hexachloroethane is of low toxicity potential to birds; thus providing further support that 1,1,2-trichloroethane is anticipated to have a low toxicity potential in birds when administered under realistic conditions." Ex. B at 10. As this subchronic study helps address the data gap identified in the Test Order – i.e., chronic avian toxicity – it is unclear why EPA did not identify or consider it. *Id.* at

9 (Stantec observing that "[s]ubchronic studies are routinely relied upon to extrapolate to chronic toxicity by regulatory agencies, including EPA.").

Moreover, based on its own public literature review, Stantec found three acute avian toxicity studies for 1,1,1-trichloroethane, an analogue identified by EPA, that were not otherwise acknowledged or considered in the administrative record or Test Order. Ex. B at 8-9. Importantly, these dietary studies, with two involving Bobwhite quail, "demonstrate that high concentrations/doses (which are not environmentally relevant) would need to be administered to birds to lead to toxic effects or mortality." *Id.* at 8. Thus, based on a read-across approach, 1,1,2-trichloroethane would be expected to have low toxicity potential in birds when administered orally or by inhalation. *Id.* at 9. But once again, none of these relevant data were included in the administrative record. *Id.* at 8-9.

Finally, apparently believing there were no material avian toxicity data (a point dispelled by Stantec's report), EPA instead only cited a single acute toxicity study (Elovaara, *et al.*, 1979) as justifying the need for the Test Order. Ex. A at 9. That study involved injecting high doses of 1,1,2-trichloroethane into eggs, which resulted in several embryo deaths. Ex. B at 10. However, in addition to various study design and analytical weaknesses identified by Stantec, EPA conceded in the Test Order that "the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure…" Ex. A at 9;

Ex. B at 10 (noting that this route of exposure is irrelevant to likely ecological exposure scenarios). In other words, Elovaara, *et al.* is a poor reference point upon which to require multi-generation avian testing, particularly when more relevant subchronic and acute avian test results could have been placed in the administrative record and fully analyzed.

In the end, according to Stantec, had EPA included this additional avian toxicity information for analogues in the administrative record, it could have then reached a conclusion that 1,1,2-trichloroethane is unlikely to be toxic to birds, instead of determining that the avian reproduction test is necessary. Ex. B at 6.

V. EPA Failed To Include In The Administrative Record Various Computational Tools That Could Aid In Tiered Testing And Minimize The Use Of Animals

Before issuing a test order, EPA is required to consider less burdensome tiered testing methods and alternatives to vertebrate animal testing. 15 U.S.C. §§ 2603(a)(4), (h). Tiered testing is often used to determine whether more costly and time-consuming studies are necessary. "Tiered testing" under section 4 includes not just new studies but also "assessments of available information." 15 U.S.C. § 2603(a)(4). These can take the form of shorter duration studies (e.g., acute *in vivo* studies), non-animal toxicity tests (e.g., *in vitro* studies), or computational approaches (e.g., computer-based prediction modeling). Ex. B at 15-16. As Stantec pointed out, if the results of tiered testing indicate a low likelihood of

toxicity, then EPA and test order recipients can save time and money, as well as avoid sacrificing a large number of animals, by foregoing full-blown chronic toxicity studies.[10] *Id.*

Despite these regulatory obligations, the Test Order never explicitly discussed tiered testing options and dismissed with a mere wave of the hand any alternatives to vertebrate testing. Again, in summary fashion, the Test Order simply stated that "[n]o approved or readily available new approach methodologies (NAMs) were identified that could be used to inform the data gap for avian toxicity following chronic exposure." Ex. A at 8. But nowhere did EPA reveal in the Test Order or the administrative record which tiered testing approaches or non-vertebrate alternatives it purportedly considered. Stakeholders like the VI have been left completely in the dark as to EPA's analysis, if any.

This is untenable. Stantec was able to quickly identify several screening methods that could be initially used to confirm the low toxicity potential of 1,1,2-trichloroethane, which as discussed above is the case based on subchronic and acute toxicity studies for various analogues. For instance, Stantec found no less than six computational methods that have been recently documented to accurately

[10] Tiered testing would go a long way in meeting section 4(h)'s directive that EPA minimize vertebrate testing. Stantec estimates acute testing would involve as few as 5 birds, while reproductive toxicity testing would require over 100 birds (even before sacrificing offspring resulting from mating). Ex. B at 16.

estimate avian toxicity, including in Bobwhite quails, based on quantitative structure-activity (toxicity) relationship (QSA(T)R) models. Ex. B at 20-22. "Collectively, the studies indicate that several computational methods have been or can be developed to enable high-throughput screening level toxicity assessments of chemicals in birds." *Id.* at 20. But it does not appear that EPA considered these computational methods as part of a tiered testing approach in advance of chronic vertebrate toxicity studies, as they do not appear in the Test Order or administrative record. *Id.* at 22.

Similarly, as mentioned above, Stantec used EPA's Web-ICE application to extrapolate toxicity data from other animals and conclude that 1,1,2-tricholoethane has low acute toxicity, as well as infer based on that modeling output that the chemical also has low chronic toxicity. Ex. B at 16-20. Significantly, four additional analogues (i.e., hexachloroethane, 1,1,1,2,2-pentachloroethane, 1,1,1,2-tetrachloroethane, and 1,1,2,2-tetrachloroethane) which were not identified by EPA in the Test Order, but were identified by Stantec using EPA's own CompTox Chemicals Dashboard, proved helpful in that analysis. *Id.* at 7, 19.

Yet none of these approaches were included in the administrative record. As such, Stantec concluded that if "EPA had considered these tools in assessing the need for chronic avian testing on 1,1,2-tricholorethane, this could have impacted the decision that an avian reproduction test is necessary." Ex. B at 22.

CONCLUSION

TSCA gives EPA authority to issue test orders in support of existing chemical risk evaluations without public notice and comment. But test order authority is not absolute. As Congress made clear in section 19(b), with that right comes substantial statutory prerequisites that must be satisfied, including that the need for a test order be predicated on a complete administrative record. Simply issuing a test order because it is efficient – or "quickly" as EPA put it – is not sufficient justification standing alone for ordering expensive and time-consuming, as well as potentially unwarranted, toxicity testing. And as Stantec's report demonstrates, the majority of the relevant data here, virtually none of which were included in the administrative record, collectively point toward withdrawing the Test Order altogether or at least initially following a tiered testing approach.

Accordingly, the VI requests this Court grant its section 19(b) motion and allow it to supplement the administrative record for EPA's further consideration, all of which will ultimately facilitate judicial review of any new test order.

Dated: August 26, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Fed. R. App. P. 27(d)(2) because it contains 5163 words, excluding the parts of the motion exempted by Fed. R. App. P. 32(f).

This motion complies with the typeface requirements of Fed. R. App. P. 32(a)(5)-(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman (14-point).

Dated: August 26, 2022

/s/ Eric P. Gotting

CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2022, I electronically filed the forgoing document with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Eric P. Gotting

EXHIBIT A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 24, 2022

Order Under Section 4(a)(2) of the Toxic Substances Control Act

Chemical Substance Subject to this Order:

Chemical Name: 1,1,2-Trichloroethane

Chemical Abstracts Service Registry Number (CASRN): 79-00-5

Docket Identification (ID) Number: EPA-HQ-OPPT-2018-0421[1]

Testing Required by this Order:

1. Environmental Hazard
    - Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
    - Avian Reproduction Test

Recipients of this Order:

Company Name: C-K TECH INC

Company Name: KEM KREST LLC

Company Name: FORMOSA PLASTICS CORP USA

Company Name: HAAS GROUP INTERNATIONAL

Company Name: OCCIDENTAL CHEMICAL HOLDING CORP

Company Name: OLIN CORP

Company Name: WESTLAKE CHEMICAL CORP

Dear Recipient:

This Order requires you and the other named manufacturer(s) and/or processor(s) of 1,1,2-trichloroethane (CASRN 79-00-5) to develop and submit certain information for 1,1,2-trichloroethane, or otherwise respond to the U.S. Environmental Protection Agency (referred to herein as "the EPA" or "the Agency"). Failure to respond to this Order, or failure to otherwise comply with its requirements, is a violation of section 15 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2614. Any person

[1] To access the docket, go to https://www.regulations.gov.

who violates TSCA shall be liable to the United States for penalties in accordance with TSCA section 16, 15 U.S.C. § 2615.

This Order is **effective 5 calendar days after its date of signature by the EPA**. The timeframes and options for responding are described in **Unit IV** (Response Options). Please note that the email transmitting this Order to you will provide the calendar date for the response deadlines as defined in **Unit III** (Deadlines for Responding to this Order). A subsequent email will provide a company specific Order number for you to use in responses and communications about this Order.

This Order is organized as follows:

I. PURPOSE AND AUTHORITY

A. OVERVIEW

This Order is being issued under the authority of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. TSCA section 4 authorizes the EPA to require the development of necessary information related to chemical substances and mixtures.

This Order requires the identified recipients to develop and submit new information on 1,1,2-trichloroethane (CASRN 79-00-5) that is necessary for the EPA to perform a risk evaluation under TSCA section 6(b).

Information on testing requirements is provided in **Appendix E**. The EPA encourages the formation of industry consortia to jointly conduct testing between the recipients of this Order. See **Unit VIII** for more information on this topic.

The Order provides four response options, listed below. More information on each of these options is provided in **Unit IV**. Timeframes for these options is provided in **Unit III**. Note that the deadline to identify as a manufacturer, processor, or both is 30 calendar days of the effective date of this Order. This step is necessary for purposes of this Order to ensure that your company can appropriately access the CDX application used for responding to section 4 orders.

Option 1: Develop the Information
Use this option to develop information in response to all of the requirements of this Order that apply to you, or use this option in conjunction with other response options identified in this section as appropriate.

Manufacturers who are required to test a chemical substance or mixture pursuant to a TSCA section 4 order are also required to pay a fee (see **Unit VII**).

Option 2: Submit Existing Information
Use this option to submit an existing study and/or other scientifically relevant information that you believe the EPA has not considered, along with supporting rationale that explains how the submittal(s) meets part or all of the information described as necessary in **Unit II**. If the Agency determines that the submitted information satisfies one or more data needs identified by this Order, the Agency will extinguish any associated test requirement(s).

Option 3: Request an Exemption
Use this option to request an exemption from a testing requirement of this Order. The EPA will grant an exemption if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement; and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

Option 4: Claim that You Are Not Subject to this Order
Use this option to claim that you are not subject to this Order. You may claim that you are not subject to this Order if all of the following are true:

1. You do not currently manufacture or process the chemical(s) identified by this Order;

2. You do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order; and

3. You have not manufactured or processed the chemical(s) at any time during the five years preceding the date of this Order.

You must provide an explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim.

B. Terminology Used in this Order

The term "manufacture" means to import into the customs territory of the United States, to produce, or to manufacture. 15 U.S.C. § 2602(9). Import also includes importing the chemical as an impurity in an article.

The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture. 15 U.S.C. § 2602(13).

The term "chemical" or "substance" means a chemical substance or mixture.

C. Persons Subject to this Order

1. Persons Identified

An order issued under section 4(a) of TSCA may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the order. The recipients of this Order are listed at the top of the Order.

For purposes of this Order, a recipient identified by this Order is subject to the Order if it has manufactured or processed the chemical at any time during the five years preceding the date of this Order. If a recipient identified by this Order has not manufactured or processed the chemical during the prior five years, the recipient is nevertheless subject to the Order if they intend to manufacture or process the chemical within the period of testing provided by this Order.

A person who contracts with a producing manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the producing manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

A recipient who is an importer of record of a chemical substance identified by this Order is responsible for the testing requirements of this Order, even if the recipient does not store, handle, use, or otherwise directly deal with the chemical.

The means by which the EPA identified each recipient subject to this Order does not govern whether a recipient is subject to this Order. Ultimately, any recipient that meets the criteria discussed in this section is subject to this Order, regardless of the basis on which the Agency identified the recipient.

2. Corporate Structure of Recipients: Changes of Ownership

The EPA has attempted to identify the highest-level U.S. corporate entity for purposes of issuing this Order. The highest-level U.S. corporate entity is ultimately responsible for satisfying the obligations of this Order, although the highest-level U.S. corporate entity may delegate its responsibilities under this Order to a U.S. subsidiary. Where the corporate entity named in this Order is not the highest-level U.S. corporate entity, the Agency nonetheless considers notification of the company named in this Order to

constitute notification of the highest-level U.S. corporate entity and holds the highest-level U.S. corporate entity ultimately responsible for satisfying the obligations of this Order.

Should you wish to modify the name of the recipient or identify another U.S. corporate entity in the corporate structure as the point of contact in place of the recipient named in this Order, you must submit a request to the EPA. Submit your request, justification for the change, and contact information for the representatives of the newly named entity to TSCAtestorders@epa.gov. A representative from the Agency will contact you and any other representatives regarding this request.

In the event of mergers, acquisitions, or other transactions that create a corporate successor in interest (subsequent to the manufacturing or processing that triggered the reporting obligation, and either before or after receipt of this Order), that successor in interest is responsible for satisfying the obligations of this Order. The successor in interest must notify the EPA of its identity within 14 days following the transaction.

D. Previously Issued Orders

The EPA previously issued a test order for 1,1,2-trichloroethane, effective January 19, 2021, to meet other data needs. See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane[2].

Since issuing that test order, the EPA's continuing review of the reasonably available information has identified additional information needed to inform the associated risk evaluation. Accordingly, the Agency is issuing this additional Order for 1,1,2-trichloroethane. See the Statement of Need for further details. This Order does not alter the requirements of any previous test orders.

II. STATEMENT OF NEED

The basis for requiring the development of new information by this Order is described in this unit and in **Appendix E**. This statement of need, as required by TSCA section 4(a)(3), includes: (A) the need for the new information; (B) how information reasonably available to the Administrator was used to inform the decision to require the new information; (C) why issuance of this Order is warranted instead of promulgating a rule or entering into a consent agreement; and (D) (if applicable) the basis for the Agency's decision to require testing of vertebrate animals. **Appendix E** (Testing Requirements of This Order) indicates which tests apply specifically to manufacturers and/or processors subject to this Order.

A. The Need for the New Information

This section and **Appendix E** explain what new information is being required in this Order and why such information is needed for the risk evaluation of 1,1,2-trichloroethane under TSCA section 6(b).

The EPA has identified the following information in this section as necessary to conduct a risk evaluation to determine whether 1,1,2-trichloroethane presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use (COU).

[2] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane*

The next unit will outline how the EPA came to determine these new information needs. Note that additional details for these testing requirements are provided in **Unit V** and **Appendix E**.

1. Environmental Hazard

Information on hazards to aquatic and terrestrial organisms is needed to conduct a risk evaluation. The relevant environmental hazard data needs that this Order seeks to address for 1,1,2-trichloroethane, as described below, are as follows:

- Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)
- Avian Reproduction Test

B. How Information Reasonably Available to the Administrator Was Used to Inform The Decision to Require New Information

This section details the "Scoping and Conceptual Models" and "Systematic Review of Reasonably Available Existing Information" processes used by the EPA to identify, respectively, what information is reasonably available to integrate into the risk evaluation for the conditions of use of 1,1,2-trichloroethane and ascertain, via a "Discipline-Specific Approach for Identifying Data Needs" what needed information is not reasonably available in existing literature (i.e., what testing to require).

1. Scoping and Conceptual Models

The *Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane* (https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf[3]) (hereinafter "*Final Scope*") includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane. The Agency has used the scope document and the conceptual models therein for workers and occupational non-users (ONUs), consumers and bystanders, general population, and environmental releases as a starting point for identifying information needs under this Order. The conceptual models visually represent the human and environmental exposures (pathways and routes), receptors, and hazards associated with the conditions of use of 1,1,2-trichloroethane. For each exposure (pathway and route), receptor, and hazard that is visually represented, the EPA has identified the information needed to conduct a risk evaluation for this chemical.

In addition, since publication of the *Final Scope*, the EPA has reconsidered the policy decision to exclude from the scope of TSCA section 6(b) risk evaluations certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. Based on that reconsideration, the Agency now also intends to consider in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane all of the exposure pathways portrayed in Figure 2-15 (Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)) of the *Final Scope*, and has identified the information needed for that assessment.

2. Systematic Review of Reasonably Available Existing Information

The systematic review process began with searching peer-reviewed literature databases (*e.g.*, Agricola, PubMed, Science Direct, ECOTOX Knowledgebase) for studies using 1,1,2-trichloroethane, synonyms,

[3] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf*

and trade names. The EPA also conducted a search of gray literature (*e.g.*, technical reports, reference books, dissertations, and other information not found in standard, peer-reviewed literature databases), as well as review of public comments posted to the docket for this chemical substance during the prioritization process and following publication of the draft scope document, relevant data and information submitted to the Agency under TSCA sections 4, 5, 8(e), 8(d), and For Your Information (FYI) submissions. The collected compilation of information was then screened for relevance. This process applied title/abstract screening and/or full-text screening based on screening criteria developed *a priori* for environmental hazard and consumer exposure (Population, Exposure, Comparator and Outcomes (PECO)); physical and chemical properties (Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO)) or occupational exposure literature (Receptors, Exposure, Setting or Scenario, and Outcomes (RESO)).

3. Discipline-Specific Approach for Identifying Data Needs

a. Environmental Hazard

The EPA defined the pathways and routes of exposure, receptors, and hazards for environmental releases and wastes that are expected to be evaluated in the *Final Scope* (Figure 2-15 pg. 44). As noted above, since publication of the *Final Scope*, the Agency has reconsidered the policy decision to exclude from the scope of TSCA section 6(b) risk evaluations certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. The Agency intends to consider all aquatic and terrestrial exposure pathways in the TSCA section 6(b) risk evaluation for 1,1,2-trichloroethane, and has identified the information needed for that assessment.

As determined in the *Final Scope*, the manufacturing, processing, distribution, use and disposal of 1,1,2-trichloroethane can result in releases to the environment and exposure to aquatic and terrestrial organisms. The EPA expects to assess environmental hazards and risks to both aquatic and terrestrial plants, invertebrates, and vertebrates and therefore requires hazard data for each of these assessment endpoints. The Agency also expects to assess organisms for both aquatic and terrestrial hazard when those organisms transition between aquatic and terrestrial ecosystems depending on the life stage evaluated (e.g., midges inhabit sediment as larvae but mature into adults that inhabit terrestrial and aquatic ecosystems).

Identification of the reasonably available information for 1,1,2-trichloroethane included consideration of existing data for the parent chemical and analogous chemicals for aquatic and terrestrial exposure pathways. The EPA identified seven analogues to 1,1,2-trichloroethane using EPA's Analog Identification Methodology (AIM) software (see **Unit II.B, Environmental Hazard – Analogues Table**). The Agency identified existing measured environmental hazard data for aquatic and terrestrial species for 1,1,2-trichloroethane and the identified analogues from the EPA's ECOTOX Knowledgebase (ECOTOX) and information submitted under TSCA, (e.g., under Sections 4 and 8e), FIFRA, and the Endocrine Disruptor Screening Program (EDSP).

Pursuant to this Order, the EPA is requiring data be submitted to facilitate evaluation of risk to terrestrial organisms. An order requesting testing to fill the aquatic data gaps identified for 1,1,2-trichloroethane was issued previously (see **Unit XI, References**). As shown in the table below, terrestrial environmental hazard data were identified for 1,1,2-trichloroethane and two of the seven identified analogues. These data covered exposures of 1,1,2-trichloroethane to terrestrial vegetation, acute exposures to soil invertebrates, mammals, and birds, and chronic exposures to mammals. No toxicity data for chronic exposures to soil invertebrates or birds were identified.

Table 1. Terrestrial Environmental Hazard – Analogues

Chemical Name	CASRN	Environmental Hazard Data Availability for 1,1,2-Trichloroethane						
		Acute Exposure			Chronic Exposure			Vegetation
		Soil Invertebrate	Mammal	Bird	Soil Invertebrate	Mammal	Bird	
1,1,2-Trichloroethane	79-00-5	X	X	X	-	X	-	X
Analogues for 1,1,2-Trichloroethane								
1,1,1-Trichloroethane	791-55-6	X	X	X	-	-	-	X
Trichloroethane	25323-89-1	-	-	-	-	-	-	-
1,2,3-Trichloropropane	96-18-4	-	X	-	-	-	-	-
1,2,3,4-Tetrachlorobuta-1,3-Diene	1637-31-6	-	-	-	-	-	-	-
1,1,5,5-Tetrachloropentane	17655-64-0	-	-	-	-	-	-	-
1,1,2,3-Tetrachloropropane	18495-30-2	-	-	-	-	-	-	-
1,2,3,4-Tetrachlorobutane	3405-32-1	-	-	-	-	-	-	-

X signifies data were identified and "-" signifies a gap, where no data were identified

C. Why Issuance of this Order is Warranted Instead of Promulgating a Rule or Entering Into a Consent Agreement

The EPA is using its order authority under TSCA section 4(a)(2) to inform the risk evaluation for 1,1,2-trichloroethane under TSCA section 6(b) in accordance with the requirements and timeframes for conducting the risk evaluation. Use of this TSCA section 4(a)(2) authority will allow the Agency to target known manufacturer and processor recipients to obtain the needed information more quickly than if the EPA were to issue a TSCA section 4 rulemaking or consent agreement.

D. The EPA Determined that Vertebrate Testing is Needed in this Order

The EPA has determined that vertebrate testing is needed to assess the particular exposure pathways and receptors discussed in this Order. Reasonably available data, computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing required by this Order (see below for details). The analysis for determining data needs described in **Unit II.B** included use of acceptable new approach methodologies (NAMs), specifically the EPA computational toxicology and informatics tools such as AIM, to identify analogues with existing information that could potentially fill data needs. A list of the testing on vertebrates required by this Order as well as further information on the EPA review process that led to the inclusion of such testing requirements can be found in **Unit II.B** and **Appendix E**, as well as below.

1. Environmental Hazard: Avian Reproduction Test

No avian toxicity data following chronic exposures were identified for 1,1,2-trichlorethane or identified analogues for any endpoints. No approved or readily available new approach methodologies (NAMS) were identified that could be used to inform the data gap for avian toxicity following chronic exposure. Without toxicity data, the EPA is unable to determine if chronic exposures to 1,1,2-trichlorethane pose a risk to terrestrial vertebrates. Office of Pesticide Programs recently released a guidance that describes instances where sub-acute dietary testing in birds may be waived (U.S. EPA, 2020). This waiver specifically outlines instances where the

animal testing burden can be reduced by requesting only acute testing oral testing in birds and waiving the traditional requirement for both acute oral testing and sub-acute dietary testing with avian species. As this Test Order does not request acute oral testing with birds nor sub-acute dietary testing with birds, this waiver request is not relevant. The Agency has worked to ensure that the animal testing burden under TSCA is reduced by utilizing all available ecotoxicity data and tailoring data needs to the specific properties of each chemical. The testing requirement is reinforced by avian toxicity data captured in the peer-reviewed literature undergoing systematic review, which qualitatively indicates exposure to 1,1,2-trichloroethane caused developmental toxicity to chick embryos (Elovaara, 1979). While the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure, the evidence of teratogenicity in chick embryos indicates that additional data are needed to understand the potential effect following chronic dietary exposure. Monitoring data from USGS's National Water Quality Monitoring Council has also identified 1,1,2-trichloroethane in media to which terrestrial vertebrates could be exposed, including ground water, sediment, soil, surface water and biota (USGS, 1991).

III. DEADLINES FOR RESPONDING TO THIS ORDER

This section describes the deadlines for this Order and possible modifications to such deadlines.

A. Deadlines for Responses to this Order

The table below provides the deadlines for this Order. Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday. Descriptions of these response options and the required process associated with each option is provided in **Unit IV**.

Table 2. Deadlines for Responses, Study Plans, and Test Reports

Order Requirement	Recipient's Deadline (Days after the effective date of the Order)	EPA Response Deadline*
• Identify as a Manufacturer, Processor or Both	30	n/a
• Submit Request to Modify Corporate Identity Identified	30	n/a
• Choose to Submit Existing Data (Option 2)	30	45
• Claim that You Are Not Subject to this Order (Option 4)	45	60
• Choose to Develop the Information - On Own or as Part of a Consortium (Option 1)	65	n/a
• Request an Exemption (Option 3)	65	80
• Submit Draft Study Plan	80	95
• Submit Final Study Plan	110	125
• Submit Final Test Report	Deadline varies per Test Requirement (See **Unit V** and **Appendix E**)	

*See **Unit III.B** for potential automatic extensions associated with the EPA responses. Deadlines for submitting final test reports for each required test are provided in **Appendix E**.

B. Automatic Extensions to Deadlines

The EPA will automatically extend deadlines should the Agency fail to meet any EPA response deadline set forth in **Unit III.A**. Specifically, deadlines will be automatically extended should the

Agency fail to respond within 15 calendar days of the deadline for a response option if the response was submitted in the CDX application prior to the deadline provided. For each day exceeding the 15-day period following the associated deadline, the EPA will extend subsequent deadlines by one day.

Should a recipient amend their response, at any time, the EPA will not extend any associated or subsequent deadlines. Therefore, the Agency recommends that recipients submit their amendments or extension requests as early as practicable to ensure adequate time to perform any required testing given that the Agency will not automatically extend deadlines for any such amendments to responses.

The EPA will not automatically extend a deadline for a response should the recipient submit its response after the deadline for the given response option. Additionally, the EPA will not automatically extend a deadline for a response should the Agency respond within 15 days of the deadline for a given response option that was submitted on or before the deadline for that response option.

Other than potential automatic extensions to deadlines described here, **Unit III.C** provides the process for requesting an extension to a deadline.

C. Requesting An Extension To A Deadline For Responding To This Order

If you believe you cannot submit the required identification as a manufacturer, processor, or both; Order response; draft study plan; final study plan; or final test report to the EPA by the deadline(s) specified in this Order and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency through the EPA's CDX portal as soon as you know you may need an extension. Your request must include: (1) a detailed description of the expected difficulty, including technical and laboratory difficulties, and (2) a proposed schedule including alternative dates for meeting such requirement(s) on a step-by-step basis.

The EPA will grant or deny deadline extension requests at its discretion.

IV. RESPONDING TO THIS ORDER

You are required to respond to this Order even if you believe your company is not subject to this Order. Failure to provide a response is a violation of section 15 of TSCA.

A. Identify As A Manufacturer, Processor, Or Both

Within 30 calendar days of the effective date of this Order, you, as a recipient of this Order, are required to respond to this Order through the EPA's Central Data Exchange (CDX) portal, informing the Agency whether you will be responding to this Order as manufacturer or processor (if you manufacture and process the chemical, select manufacturer). To provide your preliminary response to this Order, you will receive an e-mail from the EPA within five days of the Order being signed (i.e., by the effective date of the Order) that provides a CDX Order number for purposes of complying with this Order.

You may claim that you are not subject to this Order if you (1) do not currently manufacture or process the chemical(s) identified by this Order; (2) do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and (3) have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order. See **Unit VI.B.4** for more information on how to claim that you are not subject to this Order.

B. Four Response Options

A recipient has four available options for purposes of responding to this Order. See **Unit III** to review the deadlines for this Order.

Option 1: Develop the Information

If you choose to develop information in response to this Order, you must select this option in the CDX portal form.

For details on the steps of this response option, see **Unit VI**.

For more information on this Order's required tests, required protocols/methodologies, and deadlines for submission of test reports see **Unit V** and **Appendix E**.

Option 2: Submit Existing Information

If you choose to respond to this Order by submitting an existing study and/or other scientifically relevant information that you believe the EPA has not considered, your response in the EPA's CDX portal must be submitted to the EPA 30 days after the effective date of the Order and include the study(ies) and/or other scientifically relevant information, along with supporting rationale that explains how the study and/or other scientifically relevant information meets part or all of the information or obviates the need for the information described as necessary in **Unit II**.

The EPA's determination regarding whether the study and/or other relevant information satisfies part or all of the information or obviates the need for the information described as necessary in **Unit II** will be based on the weight of the scientific evidence from all relevant information reasonably available to the Agency. The Agency will notify you of its determination through CDX. If the Agency determines that the study and/or other scientifically relevant information satisfies the need in lieu of the testing required in this Order and/or the original testing requirement is no longer needed, the EPA will extinguish those testing obligations from this Order that are no longer necessary, with respect to the appropriate recipients of this Order. If the study was your only testing obligation under the Order, all your obligations under this Order will be extinguished upon notification by the Agency.

If the EPA determines that the study and/or other scientifically relevant information does not satisfy that need, you must modify your response in the EPA's CDX portal to choose one of the other response options in **Unit IV** within 10 calendar days of being notified by the Agency.

Note that the submission of existing information will not extend the deadline for the draft study plan submission for that testing requirement unless the existing information is submitted within 30 days of the effective date of the Order and the EPA does not respond within 45 days of the effective date of the Order. Thus, failure to submit existing information prior to the 30-day deadline will result in a need to submit a draft study plan by the 80-day deadline. See Unit **III.B** for information on the potential automatic extension of deadlines.

Option 3: Request an Exemption

Any person required by this Order to conduct tests and submit information on a chemical may apply for an exemption from such requirement (TSCA section 4(c)(1)).

The EPA will grant a request for exemption from the requirement to conduct tests and submit information on a chemical substance if:

1. Information on the subject chemical or an equivalent chemical has been submitted in accordance with a rule, order, or consent agreement under TSCA section 4(a), or is being developed in accordance with such a rule, order (including this Order), or consent agreement, and

2. Submission of information by the exemption applicant would be duplicative of information which has been submitted or is being developed in accordance with such rule, order (including this Order), or consent agreement.

An exemption request must be submitted through the CDX portal and contain the following:

1. This Order number, the chemical identity, and the CAS Registry No. of the test substance subject to this Order on which the application is based.

2. The specific testing requirement(s) from which an exemption is sought.

3. The basis for the exemption request when another company(ies) has/have submitted the information or is/are developing information for the subject chemical or an equivalent chemical pursuant to a TSCA section 4(a) rule, order, or consent agreement. Your request must identify the company(ies) that submitted or is/are developing the information.

4. The chemical identity of the equivalent chemical (the test substance in the information submitted or being developed) on which the application is based.

5. The equivalence data ("chemical data or biological test data intended to show that two substances or mixtures are equivalent" (see **Appendix A**)), if data on an equivalent chemical is being submitted.

6. The name, mailing address, telephone number, and e-mail address of applicant.

7. The name, mailing address, telephone number, and e-mail address of appropriate individual to contact for further information.

8. A Statement of Financial Responsibility: The following sworn statement (i.e., signed and notarized) must accompany each request for an exemption:

> "I understand that if this application is granted, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit information and upon whose information the granting of my application was based."

The EPA's grant of an exemption is conditional upon the completion of the required tests according to the specifications of this Order (or other applicable rule, order, or consent agreement), including any modifications approved by the Agency. If the EPA subsequently determines that equivalent data has not been submitted in accordance with the applicable rule, order, or consent agreement, the Agency will provide notice through CDX of its preliminary decision to terminate the exemption. Within 30 days after receipt of such notice, the exemption holder may submit information in the CDX portal either to rebut the EPA's preliminary decision to terminate the exemption or notify the Agency of its intent to develop

the required information pursuant to the specifications established in this Order and any modifications approved by the EPA. If the exemption holder submits information to rebut the EPA's preliminary decision to terminate the exemption, then the Agency will provide the exemption holder an opportunity to request a hearing prior to issuing a final decision to terminate the exemption. Following the receipt of information to rebut the EPA's preliminary decision and any subsequent hearing, the Agency will render a final decision on whether to terminate the exemption, taking into account information submitted to rebut the EPA's preliminary decision and information presented at any hearing, as applicable.

If you receive the EPA's preliminary decision to terminate the exemption and do not submit information to rebut that preliminary decision or request a hearing, or if you receive the Agency's final decision to terminate the exemption following the submission of information to rebut that preliminary decision or a hearing, you must resubmit a response in accordance with one of the options described in **Unit IV.B** of this Order within 30 calendar days of receipt of the EPA's decision to terminate the exemption, including as applicable the information required under **Unit V** of this Order. Failure to timely resubmit the response will constitute a violation of this Order and of TSCA section 15(1). Should the Agency terminate the exemption, a draft study plan will be due 30 days from the termination, with the final study plan being due 60 days from the termination.

If the EPA extinguishes a testing obligation pursuant to **Unit IV.B.2** of this Order, the corresponding exemption will be extinguished, as the exemption will no longer be necessary. In such a situation, companies who requested an exemption from that specific testing obligation are not required to reimburse the company that submitted existing data.

As explained in **Appendix B** on Cost Sharing, persons who receive exemptions from testing have an obligation to reimburse the person(s) who perform the required testing and submit the required information for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Normally, this is worked out by the parties involved, without the involvement of the EPA. However, if agreement cannot be reached on the amount or method of reimbursement, and the company who is entitled to reimbursement requests in accordance with the procedures in **Appendix B** that the Agency order reimbursement, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement. See TSCA section 4(c).

Option 4: Claim that You Are Not Subject to this Order

You may claim that you are not subject to this Order if you do not manufacture or process the chemical(s) identified by this Order; do not intend to manufacture or process the chemical(s) within the period of testing provided by this Order (see **Unit V**); and have not manufactured or processed the chemical(s) at any time during the five years preceding the effective date of this Order.

An explanation of the basis for your claim, along with appropriate supporting information to substantiate that claim, must accompany your response in the CDX portal so that the EPA can evaluate the claim.

Note that if your company ceased manufacturing (including import) or processing of the chemical substance(s) subject to this Order more than five years prior to the effective date of this Order, you can claim that you are not subject to this Order.

In the instance that you claim you are Not Subject to this Order, your claim must include (1) a statement explaining why your company is not subject to this Order, such as no longer importing, manufacturing

or processing the subject chemical substance (intentionally or unintentionally) within the five years prior to the effective date of this Order, and not intending to manufacture (including import) or process the chemical within the period of testing provided by this Order (see **Unit V**), and (2) the certifying statement "I certify that the statements made in this letter are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law."

If based on the evidence you provide and other evidence available to the EPA, the Agency deems your claim to be inadequately substantiated, the EPA will deny your claim, and the original requirements and deadlines in this Order will remain. If your claim is approved, the Agency will notify you that you are not subject to this Order through CDX correspondence. The EPA expects to provide such notification within 45 days of the effective date of this Order.

To select this option, you must do so within 45 days of the effective date of this Order.

V. OVERVIEW OF TESTING REQUIRED BY THIS ORDER

This unit applies to Option 1: Develop the Information and Option 2: Submit Existing Information (**Units IV.B.1** and **IV.B.2**).

Where the required protocol is an EPA guideline, the guideline is available on the EPA website at http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances[4] and from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-605-6000). This EPA website also provides information on OECD guidelines, which are also available via OECD's website at https://www.oecd.org/chemicalsafety/testing[5]. **Appendix E** provides additional sources for guidelines associated with specific testing.

The EPA reserves the right to revise this Order to extinguish specific testing obligations where existing information subsequently comes to the Agency's attention that in the EPA's scientific judgment obviates the need for specific test data required under this Order. Specific information for ordered test(s) are provided in **Appendix E**.

See **Appendix E** for details on the required test protocols.

Table 3. Entities Responsible and Deadlines for Required Testing Protocol(s)/Methodology(ies)
Deadlines that fall on a weekend or holiday will remain and will not be extended to the next weekday.

Test Names	Protocols Methodologies	Entities Responsible for Testing	Deadlines to Submit Final Reports to EPA
Environmental Hazard			
Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*)	OECD 222 (2016)	Manufacturers	215 days after effective date of the Order
Avian Reproduction Test	OCSPP 850.2300	Manufacturers	295 days after effective date of the Order

[4] http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances
[5] https://www.oecd.org/chemicalsafety/testing

VI. REQUIREMENTS OF RESPONSE OPTION 1: DEVELOP THE INFORMATION REQUIRED BY THIS ORDER

A. OVERVIEW

The draft study plan is due to the EPA **80 days** after the effective date of this Order. The EPA will then review the draft study plan and provide input to ensure adequacy of the final study plan. For the final study plans and the final test reports, see the Deadlines for Responses, Study Plans, and Test Reports table in **Unit III.A**.

All testing described in **Unit V** must be conducted in accordance with the Good Laboratory Practice (GLP) standards in 40 CFR part 792, as specified in the CFR on the Effective Date of this Order. You must provide a statement of compliance with these GLP standards when submitting information to the EPA pursuant to this Order.

Deviations from the test guideline or specific GLP standards are allowed provided justifications for such deviations are approved by the EPA. A justification is required for each deviation. Justifications should demonstrate that, despite the deviation from the given test guideline or GLP standard, that data integrity, control of bias, and study quality will be maintained with similar effectiveness. Any requested deviations and corresponding justifications must be included in the draft study plan for the Agency's consideration and, if approved, described in the test report.

Once the EPA has completed its review of the submitted test reports and accepts the information as fully complying with your testing obligations under this Order, the Agency will notify you.

B. DRAFT STUDY PLAN REQUIREMENTS

1. Study Plan Requirements for All Categories of Tests

If you choose to develop the required information to comply with this Order, you must obtain and review the required protocols/methodologies. **Unit V** and **Appendix E** provide the protocols/methodologies that must be followed to perform each required test.

If questions and/or issues arise during Study Plan development, the EPA encourages questions/comments be submitted along with the Study Plan submission in accordance with the draft study plan deadline. If the Agency's review of the draft study plan that includes the questions/comments is delayed, the procedure outlined in **Unit III.B** will be followed for automatic extensions of the study plan.

In addition to requirements provided in **Appendix E** for a given test required by this Order, the Study Plans must contain the following information:

1. This Order number, excluding the unique 6-digit company number using X's in place of the unique company number so as to protect each company's private access to the reporting module via Central Data Exchange (CDX). For example, if your Order number is TO-2020-0000-438435-00-0 then provide this number in the Study Plan: TO-2020-0000-XXXXXX-00-0.

2. Name of test to be covered by the test protocol/methodology.

3. The name/number of the protocol/methodology identified in this Order which you intend to follow, a copy of the identified protocol/methodology with your proposed modifications, or a copy of the alternate protocol/methodology you propose to use. Justification(s) must be provided for any deviation from the protocol/methodology provided in this Order.

4. The identity of and supporting data on the chemical substance to be tested including physical constants, spectral and chromatographic data, chemical analysis, and stability under test and storage, and test conditions required by the protocol. A Certificate of Analysis of the test substance must be provided.

5. The sampling and analytical method that will be used.

6. A description of the preparation and processing of samples that will be done before sampling and during sampling, including equilibration, weighing, calibration, test conditions (temperature, humidity), number and type of samples, and identification of equipment and accessories used (make, model, size/capacity, and operating conditions), including the specific sampling media and sampling instruments that will be used.

7. A description of all quality assurance and quality control protocols used.

8. The name(s) and address(es) of the company(ies) sponsoring the test and whether they comprise a testing consortium.

9. The name(s), mailing address(es), phone number(s), and e-mail address(es) of the appropriate individual(s) for the EPA to contact concerning the planned test.

10. The name of the testing facility and the names, mailing addresses, telephone numbers, and email addresses of the testing facility's administrative officials, study director/project managers and quality control officer responsible for ensuring the testing protocol follows appropriate quality assurance and quality control procedures.

2. Modifying a Required Protocol/Methodology in a Draft Study Plan

The draft study plan must include the required protocols/methodologies outlined in **Unit VI.A.1** and **Appendix E**. If you believe modifications of these required protocols/methodologies are necessary, you should propose the modification in the draft study plan and submit to the EPA with request for the Agency to consider the modifications. Any consultation regarding modifications to the required protocols/methodologies will not extend the deadline for submission of the draft study plan.

Any submitted requests for modifications of the required protocols/methodologies must include a detailed description of the proposed modification as well as a detailed description of the justification and reasoning for such modifications. Requests for modifications of protocol/methodology or the use of an alternate protocol/methodology must discuss why such changes are appropriate and whether they could alter the validity of the study. The rationales do not have to be listed in a separate document in the study plan if they are included and clearly identified in the relevant section of the study plan describing the protocols/methodologies.

If the EPA has concerns about the requested protocol/methodology or your requested modifications of the required protocol/methodology, the Agency will inform you of concerns that must be addressed before the EPA will approve your study plan. The Agency has 15 days from the deadline for the study

plan to respond. For each day following this period that the EPA does not respond, the Agency will extend the deadline for the final study plan by one day (see **Unit III**).

3. EPA Review of Study Plans and Final Test Report

The EPA will not conduct a substantive review of any draft study plan that does not meet the requirements as provided in **Unit IV.B.1** and **Appendix E**. Such a submission does not constitute meeting the deadline for the draft study plan submission. **Unit III** provides information on deadlines and the EPA response timelines.

Failure to submit a draft study plan, final study plan, and final test report which do not fully comply with the terms of this Order and by the deadlines provided in **Unit III** may result in a violation of TSCA section 15.

a. Study Plans

Following review of a draft study plan submission, the EPA will indicate what modifications, if any, are required and must be incorporated into the final study plan. Accompanying a proposed final study plan submission, the submitter must provide a clean and red-lined version. The red-lined version will indicate the changes incorporated into the final study plan as compared with the draft study plan submission.

If the EPA requires modifications to a submitted draft study plan, the Agency may elect to provide a line-by-line list of comments that must be addressed and corrected before a final study plan will be approved. If the submitter receives a line-by-line list of comments, the submitter must address each individual comment and include this in their response to the Agency along with the proposed final study plan.

Prior to initiating any test, the Company/Consortium must first address the EPA's input on the study plan and receive the Agency's acceptance of the final study plan.

The EPA's acceptance of a final study plan does not constitute pre-acceptance of any future test results. If testing conducted according to a requested protocol/methodology or requested modifications of the required protocol/methodology is initiated prior to EPA approval, that testing will not satisfy the requirements of the Company under this Order.

If, after the final study plan has been approved or after testing is underway, you wish to make a modification to an identified protocol/methodology or use a different protocol/methodology, you must submit a request to the EPA to make these changes in your study and you must still meet the deadlines set out in **Unit V** and **Appendix E** for the relevant test or request an extension (see also **Unit III.C**), if needed.

Note that submitting questions to the EPA regarding study plan requirements will not extend the deadline for a study plan submission.

b. Final Test Reports

Once the EPA has completed its initial review and accepted data for all test reports subject to this Order for a given testing requirement, the Agency will notify the designated contact for the company or consortium subject to this Order that this testing requirement has been satisfied, which in turn will close out the testing requirement of this Order for the companies and participants in any consortium subject to

this Order. Failure to file a final test report meeting all the requirements in this Order by the deadline in **Unit III** is a violation of TSCA. Your final test report must be submitted along with the data in the associated Organisation for Economic Co-operation and Development (OECD) harmonized template format, if available. OECD harmonized templates can be located at https://www.oecd.org/ehs/templates/harmonised-templates.htm[6]:

Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222 (2016)

- Harmonized Template Identifier: 50-1

Avian Reproduction Test (OCSPP 850.2300)

- Harmonized Template Identifier: 53

VII. FEES FOR SUBMITTING INFORMATION

Per 40 CFR § 700.45, and taking into account the inflation adjustment that went into effect on January 1, 2022, the Test Order fee is $11,650 to be split evenly among the manufacturers who are required to test a chemical substance or mixture subject to the Test Order (accounting for small business considerations). Processors are not subject to this fee, nor are manufacturers who submit existing information or receive an exemption in compliance with this Order.

Small businesses may be subject to no more than 20% of the amount of the applicable fee. A company may qualify for a "small business concern" discount if their total number of employees is at or below the maximum allowed in the final rule for that company's North American Industry Classification System (NAICS) code (see 40 CFR 700.43). In order for an entity to qualify as a "small business concern," its number of employees shall not exceed the size standard for the applicable industry. When calculating the number of employees, the company must include the employees of all parent and subsidiary companies within the corporate chain. Please note that small business fees are only applicable to qualifying small businesses who are either not associated with a consortium or associated with an all-small business consortium. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses[7].

A company can identify itself as a small business when responding to this Order via the CDX application. The "small business concern" discount will be included in the determination of company-specific invoices for the distribution of the $11,650 fee across all manufacturers conducting testing for the given Test Order. Where a consortium is responsible for the fee for its members for purposes of this Order, and at least one of the members is not a small business, the EPA does not apply a "small business concern" discount to the portion of the $11,650 distributed to the consortium.

Fees for Test Orders under TSCA section 4 will be invoiced electronically by the EPA. Invoice notices will be populated into the specific user's "Copy of Record" screen in CDX and will contain a button that will initiate the payment process. When an invoice is generated, notification e-mails will be sent to the user's CDX inbox and the e-mail address associated with the relevant CDX account. Payment information will be collected in CDX and then submitted to Pay.gov for processing.

[6] *https://www.oecd.org/ehs/templates/harmonised-templates.htm*
[7] *https://www.epa.gov/tsca-fees/tsca-fees-and-small-businesses*

Note that there are many fees associated with TSCA-related activities. See this webpage for more information: https://www.epa.gov/tsca-fees/tsca-fees-table[8]. The TSCA section 4 Test Order fee is separate from these fees. A company's inclusion in or exclusion from other TSCA fees is unrelated to that company's status with regards to TSCA section 4 Test Order fees.

Pursuant to 40 CFR § 700.45, the applicable fee shall be paid in full no later than 120 days after the effective date of the Order. Should the EPA invoice the fee more than 90 days after the effective date of the Order, payment will be due within 30 days of such invoicing.

VIII. INSTRUCTIONS IF YOU CHOOSE TO PARTICIPATE IN A CONSORTIUM

If you choose to form or join a consortium to share in the cost of developing the required information, you (as well as the other Order recipients who are participants in the consortium) must, individually in the CDX portal, state your intention to participate in a testing consortium for each specific chemical and specific test. Consortium participants must individually respond in the CDX portal with their intent to participate before designated leads are able to add them to the consortium.

In addition, the designated lead for the consortium must submit a consortium response to the EPA in the CDX portal. The response must confirm the formation of the consortium, identify its member companies, and list the testing obligations that the consortium plans to fulfill on behalf of each company by indicating each specific test. The response must also include contact information for the designated lead of the consortium, who must be domiciled in the United States. The designated lead for the consortium must submit the response and required information on behalf of the consortium and its member companies by the deadlines listed in **Unit III.A**. Submissions made on behalf of the consortium must be in accordance with instructions in **Appendix C**. Note that a consortium lead need not be a recipient of an Order; other entities (such as trade organizations) may act as a lead and submit the information required under this Order. After the results of the last required test of this Order are submitted and the EPA accepts the information as complying with this Order, or the Agency accepts existing information submitted by the Consortium, the EPA will provide notification of compliance with this Order to this Order's recipients and the designated lead of the consortium.

Even if you agree to jointly submit the information as part of a consortium, each Order Recipient is still required to comply with this Order (with the study plan and results being submitted by the consortium) and is individually liable in the event of any failure to comply with this Order. If the consortium fails to submit the information or meet any of the requirements of this Order on your behalf, you will be in violation of this Order unless you submit the required information or meet the requirement individually.

The Agency has provided a list of the manufacturers and processors that have received this Order at the top of this Order in the Summary Information section. This list of manufacturers and processors can be used to help Order Recipients form a consortium to jointly develop information, consolidate testing and share the cost of testing. Information on cost sharing is provided in **Appendix B**.

IX. CONFIDENTIALITY

Under TSCA section 14(b)(2), health and safety studies submitted under TSCA and data reported to or otherwise obtained by the Administrator from health and safety studies are not protected from disclosure if the studies and data concern a chemical that is offered for commercial distribution, or for which

[8] *https://www.epa.gov/tsca-fees/tsca-fees-table*

testing is required under TSCA section 4 or notification is required under TSCA section 5. However, TSCA section 14(b)(2) does not apply to information that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised of the chemical subject to this Order. Therefore, some or all of the information in the studies required to be submitted under this Order might not be eligible for TSCA confidential business information (CBI) protections.

Information submitted under TSCA that you wish to have the EPA protect as CBI must be clearly identified as such when submitted. For sections of the report that are claimed as CBI, the report must be accompanied by a sanitized version of the report only removing the specific information claimed as CBI. A sanitized test report that redacts all or most of the study may be rejected by the Agency as not satisfying the requirements of this Order.

When claiming information as CBI, you must certify to the following:

"I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001."

In addition, information claimed as CBI must be substantiated upon submission, with the exception of information described in TSCA section 14(c)(2). Guidance for substantiating CBI claims may be found at https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations.

Failure to follow the statutory requirements for asserting and substantiating a CBI claim may result in the information being made available to the public without further notice to the submitter.

When a claim of CBI under TSCA section 14 is approved by the EPA, the Administrator will generally protect that information from disclosure for 10 years (unless the protection from disclosure is withdrawn by the person that asserted the claim), whereupon the claim must be reasserted and re-substantiated if the submitter wishes to maintain the CBI claim. In certain cases, the Agency may review claims prior to the expiration of the 10-year period.

Under circumstances stated in TSCA section 14(d), the EPA may disclose information claimed as CBI to other persons including, for example, Federal and State authorities, health and environmental professionals, poison control centers, and emergency responders.

X. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS ORDER

Failure to comply with any of the requirements in this Order is a violation of TSCA section 15 and could subject you to civil and/or criminal penalties under TSCA section 16, 15 U.S.C. § 2615 as modified by the Federal Civil Penalties Inflation Adjustment Act. Each day that failure to meet the requirements continues constitutes a separate violation.

XI. REFERENCES

The following is a listing of the documents that are generally applicable to this Order. **Appendix E** provides references specific to certain testing requirements in this Order. Please note that references, guidance, and information from additional sources could be considered, with EPA approval, during the development of study plans.

The docket includes these documents and other information considered by the EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

General References for this Test Order

1. U.S. EPA (2021). 1,1,2-Trichloroethane Test Order [EPA-HQ-OPPT-2018-0421]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane[9]

2. U.S. EPA (2020a). Final Scope of the Risk Evaluation for 1,1,2-Trichloroethane [EPA-740-R-20-003]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf[10]

3. U.S. EPA (2020b). Use Report for 1,1,2-Trichloroethane (CASRN 79-00-5) [EPA-HQ-OPPT-2018-042]. Washington DC: U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (OPPT). https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0421-0018[11]

Earthworm Reproduction (*Eisenia fetida/Eisenia andrei*) Test References

[9] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-4a2-test-order-112-trichloroethane*
[10] *https://www.epa.gov/sites/default/files/2020-09/documents/casrn_79-00-5_112-trichloroethane_finalscope.pdf*
[11] *https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0421-0018*

4. OECD. (2016). Test No. 222: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*). Paris, France: OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing. https://doi.org/10.1787/9789264264496-en[12]

Avian Reproduction Test References

5. Elovaara, E., Hemminki, K., Vainio, H. (1979). Effects of Methylene Chloride, Trichloroethane, Trichloroethylene, Tetrachloroethylene and Toluene on the Development of Chick Embryos. Toxicology, Volume 12, Issue 2, Pages 111-119, ISSN 0300-483X. https://doi.org/10.1016/0300-483X(79)90037-4[13]

6. U.S. EPA (2012). OCSPP 850.2300: Avian Reproduction Test [EPA 712C-023]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012[14]

7. U.S. EPA (2020). Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis. Washington DC: U.S. Environmental Protection Agency, Office of Pesticide Programs (OPP). https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf[15]

8. U.S. Geological Survey (USGS). (1991). USGS Monitoring Data: National Water Quality Monitoring Council [Database] – Air, Groundwater, Sediment, Soil, Surface Water, Tissue. http://www.waterqualitydata.us/portal/[16]

XII. PAPERWORK REDUCTION ACT NOTICE

This collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. (OMB Control No. 2070-0033). Responses to this collection of information are mandatory under the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 137 hours for the average response on a per-chemical basis. Under the PRA, burden is defined at 5 CFR 1320.3(b). Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

XIII. FOR FURTHER INFORMATION CONTACT

For technical information contact: TSCATestOrders@epa.gov.

[12] *https://doi.org/10.1787/9789264264496-en*
[13] *https://doi.org/10.1016/0300-483X(79)90037-4*
[14] *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012*
[15] *https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf*
[16] *http://www.waterqualitydata.us/portal/*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

XIV. SIGNATURE

Under the authority in TSCA section 4(a)(2), the United States Environmental Protection Agency hereby issues this Order to take effect on the date of my signature.

MICHAL FREEDHOFF
Digitally signed by MICHAL FREEDHOFF
Date: 2022.03.24 06:46:32 -04'00'

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Enclosures

APPENDIX A - EQUIVALENCE DATA

For purposes of this Order, "equivalence data" means "chemical data or biological test data intended to show that two substances or mixtures are equivalent." Also, when a chemical substance is "equivalent," it means "that a chemical substance is able to represent or substitute for another in a test or series of tests, and that the data from one substance can be used to make scientific and regulatory decisions concerning the other substance," as defined in 40 CFR § 790.3.

If testing under TSCA section 4(a) is required of an equivalent chemical substance, the EPA may grant an exemption from testing to the manufacturer or processor of one substance if the information required under TSCA section 4(a) is submitted or is being developed on the other, and the manufacturer or processor submits the following information to support equivalence with its exemption application:

1. The chemical identity of each chemical substance or mixture manufactured or processed by the applicant for which the exemption is sought. The exact type of identifying data required may be specified in this Order and may include all characteristics and properties of the applicant's substance or mixture, such as boiling point, melting point, chemical analysis (including identification and amount of impurities), additives, spectral data, and other physical or chemical information that may be relevant in determining whether the applicant's substance or mixture is equivalent to the specific test substance.

2. The basis for the applicant's belief that the substance or mixture for which the exemption is sought is equivalent to the test substance or mixture.

3. Any other data which exemption applicants are directed to submit in this Order which may have bearing on a determination of equivalence. This may include a description of the process by which each chemical substance or mixture for which an exemption is sought is manufactured or processed prior to use or distribution in commerce by the applicant.

APPENDIX B - COST SHARING

The EPA encourages Order recipients that are responsible for developing the same information on the same chemical(s) to avoid duplicative testing and share the cost of information development. If a test is conducted according to a final, approved protocol, it is sufficient that the test is conducted once. Two ways to avoid duplicative testing are discussed in this Order. They are forming or joining a consortium, discussed in **Unit VIII**, or requesting an exemption, discussed in **Unit IV.B.3**.

Consortia

Persons that form or join a consortium typically execute an agreement with the other members of the consortium concerning how costs will be shared and how the consortium will operate.

Exemptions

Persons that receive exemptions from testing have an obligation to reimburse the person(s) who perform the testing and submit the required information that is the basis for the exemption for a portion of the costs incurred in complying with the requirement to submit such information, and any other person required to contribute to a portion of such costs. Apportionment of costs between persons receiving exemptions and the person who actually conducts the test(s) is ideally negotiated between the companies involved, without the EPA's participation. The Agency has promulgated regulations that explain how the EPA views fair and equitable reimbursement in the context of TSCA section 4(a) test rules. In general, those regulations (40 CFR § 791.40 through § 791.52) make a presumption that a person's fair share of the test costs is in proportion to their share of the total production volume of the test chemical over a specified period of time that begins one calendar year before the effective date of the rule and continues up to the latest data available upon resolution of a dispute. While those regulations do not apply to TSCA section 4 orders, you may wish to consider them as you decide how to share the costs.

If persons subject to an order include a person that has been granted an exemption and agreement cannot be reached on the amount and method of sharing the cost of developing the information, the person whose information is the basis for the exemption may request that the Administrator order the person(s) granted the exemption to provide fair and equitable reimbursement after considering all relevant factors, including the share of the market and the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed. See TSCA section 4(c)(3)(A). Upon receipt of such a request, the EPA will determine fair and equitable reimbursement and issue an order accordingly. The Agency may, at its discretion, make use of procedures and standards applicable to data reimbursement regarding TSCA section 4 rules, contained in 40 CFR part 791.

APPENDIX C - HOW TO ACCESS THE CDX APPLICATION AND RECORDKEEPING REQUIREMENTS

How to Access the CDX Application

The initial response, draft and final study plans, final test reports with underlying data, existing studies, any testing related requests, and all related correspondence must be submitted electronically to the EPA as follows:

1. Submit to the EPA's CDX system. CDX is the point of entry on the Environmental Information Exchange Network (Exchange Network) for submissions to the Agency.

2. The URL for the CDX website is *https://cdx.epa.gov/*[17] which takes you to the CDX homepage.

3. On the homepage you may select "Log in" or, if you haven't already registered, select "Register with CDX."

4. Once you have logged on to CDX, follow the instructions for submitting TSCA section 4 order information. To access the instructions, select "Report electronically" on the EPA Internet homepage at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*[18].

5. The CDX Help Desk is available for data submission technical support between the hours of 8:00 am and 6:00 pm (EST) at 1-888-890-1995 or helpdesk@epacdx.net. The CDX Help Desk can also be reached at 970-494-5500 for international callers.

The EPA may revise these submission instructions with advance notice.

Recordkeeping

You must retain copies of all information documenting your compliance with this Order for ten years. This includes your response and other documents and correspondence submitted to comply with this Order, such as test protocols, testing related requests, final test reports with their underlying data, and any penalties remitted.

[17] *https://cdx.epa.gov/*
[18] *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information#data*

APPENDIX D - ORDER RECIPIENT SELECTION

This Appendix describes the process by which the EPA identified recipients of this Order. This information is for your use, and does not govern the obligations under this Order or the identities of the companies subject to this Order. A recipient of this Order that manufactures or processes the chemical as per the definitions provided in **Unit I.B** is subject to this Order, regardless of the basis on which the Agency identified the recipient.

The manufacturers and processors of the chemical subject to this Order were determined in the following manner:

The EPA included in this Order as recipients all companies comprising the final list of manufacturers subject to fee payments[19] for *p*-dichlorobenzene developed under the "Fees for Administration of Toxic Substances Control Act" rule in 2020, as well as, manufacturers identified by other sources, including Toxics Release Inventory[20] (TRI) reporting from 2016 to 2020 and Chemical Data Reporting (CDR) reporting from 2020. The Agency also included in this Order Companies who reported as "Processors" of this chemical to the 2016 to 2020 TRI. Although the EPA recognizes that there are processors who do not report to TRI, this database was used to identify processors for the purposes of this order because it is the Agency's most comprehensive source to establish a well-verified list of processing companies.

[19] *https://www.epa.gov/tsca-fees/final-list-fee-payers-next-20-risk-evaluations*
[20] *https://www.epa.gov/toxics-release-inventory-tri-program*

APPENDIX E - SPECIFIC REQUIREMENTS AND GUIDANCE FOR THIS ORDER

This appendix provides requirements of study plans and test reports for specific testing requirements of this Order. Additionally, this appendix provides additional reference material(s) associated with the testing required in this Order.

For information on how the EPA determined the need for the testing requirements of this Order, refer to **Unit II.B.**

I. Environmental Hazard

a. Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD 222 (2016)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to OECD 222 include:

1. Final exposure concentrations must capture both lethal and sub-lethal effects over a period of 8-weeks, such that they bracket the Effective Concentration (ECx) estimate. To ensure these requirements are met, it is highly recommended that a range finding test is conducted before the initiation of the definitive test.

2. Soil must be mixed and homogenized with the chemical, and the source, purity, and a Certificate of Analysis of the test substance must be reported. The draft study plan will not be approved by the EPA without the purity of the test material.

3. The analytical laboratory must describe how they will conduct analytical verification of the test material at the beginning and end of the test, and every 7-days throughout the test duration.

4. A description must be provided as to whether the use of formulated/artificial or field-collected soil is being implemented (the EPA recommends formulated/artificial soil).

5. An outline must be provided of the raw data to be collected for each sub-lethal and lethal endpoint as well as statistical analyses that are planned.

6. Because 1,1,2-trichloroethane is a volatile substance, a description must be provided as to how the test laboratory will account for volatilization.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 215 days after effective date of the Order and must include the following, as applicable:

1. Harmonized Template ID: 50-1

2. Harmonized Template URL: https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm[21]

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. OECD (Organisation for Economic Co-operation and Development). (2016). Test No. 222: Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*). Paris, France: OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing. https://doi.org/10.1787/9789264264496-en[22]

b. Avian Reproduction Test (OCSPP 850.2300)

i. Study Plans

Please see **Unit VI.B** of the Order for overall requirements for study plans. Additional requirements specific to OCSPP 850.2300 include:

1. An outline must be provided of the raw data to be collected for each sub-lethal and lethal endpoint as well as statistical analyses that are planned.

2. The study laboratory must describe how they will conduct analytical verification of the test material in the diet at the beginning, middle and end of the test to ensure exposure, and the source, purity, and a Certificate of Analysis of the test substance must be reported. The draft study plan will not be approved by the EPA without the purity of the test material.

3. A description should be provided as to how frequently the test diets will be mixed, to ensure for volatile substance that the concentrations are not reduced from initial concentrations by more than 20%.

4. The Northern bobwhite (*Colinus virginianus*) must be used instead of the mallard (*Anas platyrhynchos*) or other test species recommended in the guideline, because it is less prone to regurgitation and easier to measure food consumption for this species.

ii. Test Reports

In addition to the requirements provided by **Unit VI**, test reports submitted to the EPA are due 295 days after effective date of the Order and must include the following, as applicable:

1. Harmonized Template ID: 53

2. Harmonized Template URL: https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm[23]

[21] *https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm*
[22] *https://doi.org/10.1787/9789264264496-en*
[23] *https://www.oecd.org/ehs/templates/harmonised-templates-effects-on-biotic-systems.htm*

iii. References

In addition to generally applicable references provided by **Unit XI**, the following is a list of references specific to this testing requirement:

1. Elovaara, E., Hemminki, K., Vainio, H. (1979). Effects of Methylene Chloride, Trichloroethane, Trichloroethylene, Tetrachloroethylene and Toluene on the Development of Chick Embryos. Toxicology, Volume 12, Issue 2, Pages 111-119, ISSN 0300-483X. https://doi.org/10.1016/0300-483X(79)90037-4[24]

2. U.S. EPA (2012). OCSPP 850.2300: Avian Reproduction Test [EPA 712C-023]. Washington DC: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012[25]

3. U.S. EPA (2020). Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis. Washington DC: U.S. Environmental Protection Agency, Office of Pesticide Programs (OPP). https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf[26]

4. USGS. (1991). USGS Monitoring Data: National Water Quality Monitoring Council [Database] – Air, Groundwater, Sediment, Soil, Surface Water, Tissue. http://www.waterqualitydata.us/portal/[27]

[24] *https://doi.org/10.1016/0300-483X(79)90037-4*
[25] *https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0012*
[26] *https://www.epa.gov/sites/default/files/2020-02/documents/final-waiver-guidance-avian-sub-acute-dietary.pdf*
[27] *http://www.waterqualitydata.us/portal/*

EXHIBIT B

Assessment of Determination of Need for Avian Reproduction Testing for 1,1,2-Trichloroethane: Critique of EPA's Approach and Conclusion

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now

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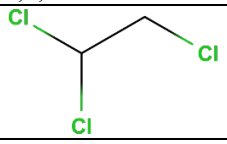
Table of Contents

1. BACKGROUND

1.1. Overview of 1,1,2-Trichloroethane

1,1,2-Trichloroethane is predominantly an anthropogenic chemical, and its presence in the environment is due to human activity. It is synthesized via the chlorination of ethylene with chlorine or by the oxychlorination of ethylene with hydrochloric acid and oxygen. It is primarily used as a captive intermediate in the production of 1,1-dichloroethene, but could also be used as a solvent, especially in chlorinated rubber manufacture (ATSDR, 2021). The physiochemical properties of 1,1,2-trichloroethane are provided in **Table 1**.

Table 1. Physiochemical properties of 1,1,2-trichloroethane.

Property	Attribute
Chemical name	1,1,2-Trichloroethane
Chemical structure[†]	
Chemical abstracts number[‡]	79-00-5
Molecular formula[‡]	$C_2H_3Cl_3$
Molecular weight (g/mol)[‡]	133.4
Physical description[‡]	Clear, colorless, sweet-smelling liquid
Vapor pressure (mmHg)[*]	23.0 (experimental)
Melting point (°C)[*]	-36.4 (experimental)
Boiling point (°C)[*]	114 (experimental)
Water solubility (mol/L)[*]	3.35×10^{-2} (experimental)
Log K_{ow}[*]	1.98 (experimental)
Henry's law constant (atm-m^3/mol)[*]	8.24×10^{-4} (experimental)
Density (g/cm^3)[*]	1.36 (predicted)

Sources: [†]MolView (https://molview.org/); [‡]PubChem (https://pubchem.ncbi.nlm.nih.gov/compound/6574); [*]CompTox Chemicals Dashboard (https://comptox.epa.gov/dashboard/chemical/details/DTXSID5021380)

1.2. Test Order

In December 2019, 1,1,2-trichloroethane was designated as a high priority substance for risk evaluation following the process required by section 6(b) of the Toxic Substances Control Act (TSCA) (EPA, 2020). More recently, a test order has been issued by the U.S. Environmental Protection Agency (EPA). The test order includes a requirement to conduct an avian reproduction test (EPA, 2022a). As explained by the EPA, *"The testing requirement is reinforced by avian toxicity data captured in the peer-reviewed literature undergoing systematic review, which qualitatively indicates exposure to 1,1,2-trichloroethane caused developmental toxicity to chick embryos (Elovaara, 1979)."* The EPA recognized that *"the nature of this endpoint (egg injection) is not directly comparable to other chemical toxicities following dietary exposure"*; however, *"the evidence of teratogenicity in chick embryos indicates that additional data are needed to understand the potential effect following chronic dietary exposure."* Additionally, EPA noted that *"Monitoring data from USGS's National Water Quality Monitoring Council has also identified 1,1,2-trichloroethane in media to which terrestrial vertebrates could be exposed, including ground water, sediment, soil, surface water and biota (USGS, 1991)."*

Unfortunately, the EPA did not consider all the available information when issuing the test order to require avian reproduction toxicity testing for 1,1,2-trichloroethane. Thus, this report discusses the information considered by the EPA and details the additional, readily available information that should have been

considered prior to issuing a test order, especially given EPA's obligation under TSCA to reduce and replace animal testing, and to consider first requiring less burdensome tiered testing. Specifically, the report demonstrates that (i) additional chemical analogues are available for EPA's consideration to inform 1,1,2-trichloroethane toxicity, (ii) available toxicity data for 1,1,2-trichloroethane and its analogues indicate low toxicity, (iii) computational methods are available to predict avian toxicity for 1,1,2-trichloroethane, and (iv) the potential for avian exposure is negligible given the very low detection frequency in environmental samples and the low chemical concentrations when detects occur.

1.3. Summary of Conclusions

The current report provides commentary for consideration pertaining to the Test Order Under Section 4(a)(2) of the Toxic Substances Control Act. Specifically, the report makes the following conclusions, which are detailed in **Section 3**:

- EPA neglected to consider additional analogues for 1,1,2-trichloroethane when concluding that chronic avian testing was an existing data need. Additional analogues can be identified using EPA's CompTox Chemicals Dashboard. Consideration of the available toxicity information for these analogues, as well as at least one analogue identified by EPA, could provide additional information to support an understanding of the hazards of 1,1,2-trichloroethane and obviate the need for chronic vertebrate testing.
- The environmental monitoring data EPA cited on 1,1,2-trichloroethane demonstrate that avian species would be exposed to only low levels of the substance, if at all.
- Under TSCA, EPA is required to both consider a tiered testing approach and reduce vertebrate animal testing by considering alternate methodologies. For avian toxicity testing, lower tier assays and new approach methodologies (NAMs) are available for consideration, including computational tools endorsed by the EPA, that could inform on 1,1,2-trichloroethane toxicity as a preliminary step and potentially avoid chronic vertebrate testing. EPA neglected to consider these options for 1,1,2-trichloroethane.

2. MATERIALS REVIEWED

The following materials were reviewed to formulate the opinions expressed herein:

- EPA Order Under (4)(a)(2) of the Toxic Substances Control Act for 1,1,2-trichloroethane (corrected version).
- All materials specified in the certified index.
- Independent literature review for 1,1,2-trichloroethane and its structural analogues using PubMed[1], as well as publicly available databases, including the European Chemicals Agency (ECHA) registered substances database[2], Agency for Toxic Substances and Disease Registry (ATSDR) Toxic Substances Portal[3], and EPA's ECOTOX Knowledgebase[4].
- Identification of 1,1,2-trichloroethane structural analogues using EPA's Analog Identification Methodology (AIM) as well as EPA's CompTox Chemicals Dashboard[5].

[1] https://pubmed.ncbi.nlm.nih.gov/ [keywords: (chemical name or CAS) AND (bird or avian or egg or chick or chicken)]
[2] https://echa.europa.eu/nl/information-on-chemicals/registered-substances
[3] https://wwwn.cdc.gov/TSP/index.aspx
[4] https://cfpub.epa.gov/ecotox/search.cfm
[5] https://comptox.epa.gov/dashboard/

3. DETAILED KEY POINTS

3.1. EPA neglected to consider additional analogues for 1,1,2-trichloroethane when concluding that chronic avian testing was an existing data need. Additional analogues can be identified using EPA's CompTox Chemicals Dashboard. Consideration of the available toxicity information for these analogues, as well as at least one analogue identified by EPA, could provide additional information to support an understanding of the hazards of 1,1,2-trichloroethane and obviate the need for full-blown reproductive testing.

It is well recognized that analogue analysis is an important step in the read-across approach, which refers to the use of existing or computational data for the chemical of interest and chemicals with similar structure (or analogues) to fill in data gaps. Importantly, many publicly available tools exist to identify analogues, including EPA's tools, models, and programs as well as methods available within the Organisation for Economic Co-operation and Development (OECD) Quantitative Structure-Activity Relationship (QSAR) Toolbox (EPA, 2021a).

According to the test order, the EPA identified *"seven analogues to 1,1,2-trichloroethane using EPA's Analog Identification Methodology (AIM) software"* (EPA, 2022a). However, several additional analogues not considered by EPA were identified using EPA's CompTox Chemicals Dashboard. As for available avian toxicity studies for 1,1,2-trichloroethane analogues, the EPA did not consider three acute toxicity studies for 1,1,1-trichloroethane, which demonstrated that a high chemical dose or concentration is needed to elicit toxicity (such doses/concentrations are not environmentally relevant). Further, an inhalation study for hexachloroethane (an analogue not identified by EPA) was identified, which showed that toxicity was observed only at the highest concentration, which would not be environmentally relevant. Regarding avian toxicity data for 1,1,2-trichloroethane, the EPA has identified a single study documenting developmental effects in chicken eggs injected with 1,1,2-trichloroethane. While the EPA has acknowledged that the route of exposure is not relevant, the administered doses and the potential confounding factors were not considered by the EPA when evaluating this study. The following sections discuss these points, including analogue identification, available studies for analogues, and the problematic nature of the avian study on 1,1,2-trichloroethane, in more detail.

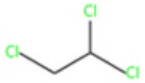
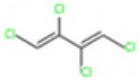
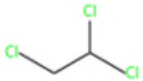
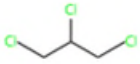
3.1.1. Analogue Identification

According to the Order Under (4)(a)(2) of the Toxic Substances Control Act (corrected version), EPA's AIM tool was used to identify structural analogues of 1,1,2-trichloroethane. The seven structural analogues identified by EPA in the test order are presented in **Table 2**. Interestingly, the analogues identified and noted in the test order deviate from the list of analogues noted in the 'No. 16_eco data gathering_aim-output_080720' file specified in the certified index. Specifically, the list does not include 1,1,1-trichloroethane as an analogue for 1,1,2-trichloroethane as depicted in **Figure 1A**. Additionally, according to the certified index, the EPA also utilized OECD QSAR Toolbox to identify analogues for 1,1,2-trichloroethane, which was not specified in the test order. As per 'No.10_Data matrix_112TCE and first pass analogues' file, the same analogues were identified using OECD QSAR Toolbox as with AIM (**Figure 1B**). Thus, it is unclear how 1,1,1-trichloroethane was determined to be an analogue, though this conclusion is reasonable given the structural and compositional similarities to 1,1,2-trichloroethane.

A

chemical	CAS RN	1st pass aim analog name	1st pass analog	1st pass analog is in 1st 1	1st pass analog is in next 20
1,1,2-TRICHLOROETHANE	79-00-5	1,2,3,4-TETRACHLOROBUTA-1,3-DIENE	1637-31-6	#N/A	#N/A
		TRICHLOROETHANE	25323-89-1	#N/A	#N/A
		1,2,3-TRICHLOROPROPANE	96-18-4	#N/A	#N/A
		1,1,5,5-Tetrachloropentane	17655-64-0	#N/A	#N/A
		1,1,2,3-TETRACHLOROPROPANE	18495-30-2	#N/A	#N/A
		1,2,3,4-TETRACHLOROBUTANE	3405-32-1	#N/A	#N/A

B

Chemical #1	Chemical #2	Chemical #3	Chemical #4
			
79-00-5	1637-31-6	25323-89-1	96-18-4
1,1,2Trichloroethane	1,2,3,4-TETRACHLOROBUTA-1,3-DIENE	TRICHLOROETHANE	trichloropropane
ClCC(Cl)Cl	ClC=C(Cl)C(Cl)=CCl	ClCC(Cl)Cl	ClCC(Cl)CCl

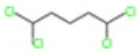
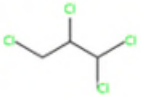
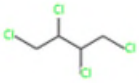
Chemical #5	Chemical #6	Chemical #7
		
17655-64-0	18495-30-2	3405-32-1
1,1,5,5-Tetrachloropentane	1,1,2,3-tetrachloropropane	1,2,3,4-tetrachlorobutane
ClC(Cl)CCCC(Cl)Cl	ClCC(Cl)C(Cl)Cl	ClCC(Cl)C(Cl)CCl

Figure 1. Screenshots of portions of EPA documents noted in certified index. A. AIM output for 1,1,2-trichloroethane analogues as per 'No. 16_eco data gathering_aim-output_080720'. B. OECD QSAR Toolbox output for 1,1,2-trichloroethane analogues as per 'No.10_Data matrix_112TCE and first pass analogs'.

Our independent analysis using the AIM (default program settings) revealed a list of six analogues; the list did not include 1,1,1-trichloroethane and 1,2,3,4-tetrachlorobuta-1,3-diene, but did include pentachlorobutane (**Table 2; Appendix A**). Further, our examination of EPA's CompTox Chemicals Dashboard, an alternate tool for identification of structural analogues, for 1,1,2-trichloroethane revealed seven *additional* potential analogues (**Table 2**) that were not considered by EPA. Based on an initial analysis of these additional analogues, at least one has relevant toxicological data, and several others proved useful in NAMs analysis. Thus, there are additional analogues of 1,1,2-trichloroethane from which EPA could leverage information about avian toxicity.

Table 2. Structural analogues identified by EPA and Cardno ChemRisk using the AIM as well as structural analogues noted on 1,1,2-trichloroethane CompTox Chemicals Dashboard page.

Source	Chemical	CAS number
AIM (EPA test order)	1,1,1-Trichloroethane	791-55-6 (CAS number as noted in test order should be corrected to 71-55-6)
	Trichloroethane	25323-89-1
	1,2,3-Trichloropropane	96-18-4
	1,2,3,4-Tetrachlorobuta-1,3-diene	1637-31-6
	1,1,5,5-Tetrachloropentane	17655-64-0
	1,1,2,3-Tetrachloropropane	18495-30-2
	1,2,3,4-Tetrachlorobutane	3405-32-1
AIM (Cardno ChemRisk)	Trichloroethane	25323-89-1
	1,2,3-Trichloropropane	96-18-4
	1,1,5,5-Tetrachloropentane	17655-64-0
	1,1,2,3-Tetrachloropropane	18495-30-2
	Pentachlorobutane	31391-27-2
	1,2,3,4-Tetrachlorobutane	3405-32-1
CompTox Chemicals Dashboard (Cardno ChemRisk)	1,1,2,2-Tetrachloroethane	79-34-5
	1,1,2,2-Tetrachloro(~13~C_2_)ethane	212266-24-5
	1,1,2,2-Tetrachloro(~2~H_2_)ethane	33685-54-0
	1,1,1,2-Tetrachloroethane	630-20-6
	1,1,1,2,2-Pentachloroethane	76-01-7
	Hexachloroethane	67-72-1
	1,1,1,2,2,2-Hexachloro(1-~13~C)ethane	93952-15-9

3.1.2. Avian Toxicity Data for 1,1,2-Trichloroethane Analogues

To understand if EPA thoroughly reviewed the available avian toxicity data for analogues of 1,1,2-trichloroethane, we separately searched for toxicity information on the analogues, including analogues not identified by EPA. From this search, additional toxicity information was identified that should have been used to inform potential avian toxicity of 1,1,2-trichloroethane. Several avian acute toxicity studies were noted for 1,1,1-trichloroethane in ECOTOX Knowledgebase. Four of the five entries referred to information available via the Pesticide Ecotoxicity Database[6]. Our search of this database revealed two entries for bobwhite quail and one entry for mallard duck (**Table 3**); these studies provided median lethal concentration (LC_{50}) or dose (LD_{50})[7] as well as no-observed-effect level (NOEL)[8]. It is noteworthy that all three studies that reported LC_{50}/LD_{50} did not observe mortality at the highest concentration/dose tested (**Table 3**). The fifth entry in ECOTOX Knowledgebase referred to a report by Dow Chemical, according to which pheasants were exposed to 1,1,1-trichloroethane via fumigation for less than a day, and the LC_{50} was noted as ~14,000 ppm. These studies all support the low toxicity potential of 1,1,1-trichloroethane.

In their evaluation, EPA noted the Dow Chemical report in the certified index (No. 275. ECOTOX 180559 Dow Chemical USA (1984) EPA/OTS 40-8424479); however, they did not acknowledge or consider the other additional acute toxicity studies for 1,1,1-trichloroethane as a surrogate for understanding avian toxicity of 1,1,2-trichloroethane (i.e., as an indication that toxicity for 1,1,2-trichloroethane would also likely be low). The available studies for 1,1,1-trichloroethane demonstrate that high concentrations/doses (which are not environmentally relevant) would need to be administered to birds to lead to toxic effects or mortality. Notably, the LC_{50}s/LD_{50}s discussed in this subsection are >2,000 mg/kg or >5,000 ppm, which would categorize 1,1,1-trichloroethane as 'practically nontoxic' using EPA's toxicity categorization chart

[6] https://ecotox.ipmcenters.org/index.cfm?menuid=5
[7] The LC_{50}/LD_{50} refers to the concentration/dose necessary to elicit mortality in 50% of animals.
[8] The NOEL refers to the dose at which no effects are observed.

for terrestrial organisms (EPA, 2008). Thus, using the read-across approach, 1,1,2-trichloroethane is anticipated to have a low toxicity potential in birds when administered orally or by inhalation.

Table 3. Acute avian toxicity studies for 1,1,1-trichloroethane identified in the Pesticide Ecotoxicity Database.

Entry	Species	Study guideline, test type, length	Toxicity thresholds
1†	Bobwhite quail	• [71-1] Avian Acute Oral-Game Bird or Waterfowl using TGAI or TEP (FIFRA 158.490) • [O] Oral gavage or capsule administration of the toxicant • 14 days	• LD_{50}: >2,510 mg/kg bw *(no mortality at highest dose)* • NOEL: 1,590 mg/kg bw
2‡	Bobwhite quail	• [71-2] Avian Dietary-Waterfowl and Game Species using TGAI or TEP (FIFRA 158.490) • [D] Administration of the toxicant ad libitum in the diet • 8 days	• LC_{50}: >5,620 ppm *(no mortality at highest concentration)* • LD_{50}: >~523 mg/kg bw§ • NOEL: 3,160 ppm (~294 mg/kg)§
3⁑	Mallard duck	• [71-2] Avian Dietary-Waterfowl and Game Species using TGAI or TEP (FIFRA 158.490) • [D] Administration of the toxicant ad libitum in the diet • 8 days	• LC_{50}: >5,620 ppm§ *(no mortality at highest concentration)* • NOEL: not reported

† https://ecotox.ipmcenters.org/details.cfm?recordID=10961

‡ https://ecotox.ipmcenters.org/details.cfm?recordID=10962

⁑ https://ecotox.ipmcenters.org/details.cfm?recordID=10963

§ The 'mg/kg' values for bobwhite quail were calculated assuming a food ingestion rate of 0.093 g/g and a body weight of 0.19 kg according to EPA (1993). For mallard duck, food ingestion rate was not provided by EPA (1993); thus, conversion to mg/kg was not performed.

In addition to the available acute toxicity studies for 1,1,1-trichloroethane not considered in the EPA evaluation, there is also an available repeated dose, subchronic study[9] for hexachloroethane (analogue that was identified via CompTox Chemicals Dashboard) that could be used to inform the specific data need identified by EPA (chronic avian toxicity) via read-across for 1,1,2-trichloroethane. In a study by Weeks et al. (1979; identified via PubMed), Japanese quails were exposed to 15, 48, or 260 ppm (approximately 145, 464, or 2,517 mg/m^3) hexachloroethane vapor for 6 hours per day, 5 days per week, for 6 weeks. The birds were observed during the 6-week exposure period and for 12 weeks post-exposure. It was reported that no mortality, clinical signs, body weight changes, or gross tissue or organ changes were observed in exposed quails; however, excess mucus was noted in two of 10 quails exposed to the highest dose. While the authors did not report the LC_{50} or the lowest-observed-effect concentration (LOEC) and no-observed-effect concentration (NOEC)[10], based on the study results, these toxicity parameters are considered to be >2,517, 2,517, and 464 mg/m^3, respectively. Subsequently, a NOEL in mg/kg/d can be estimated by considering body weight and inhalation rate for Japanese quails. While body weight and inhalation rate were not specified by Weeks et al. (1979), according to Huss et al. (2008), Japanese quails can weigh as much as 250 g (or 0.25 kg), and their inhalation rate can be estimated using **Equation 1** as per EPA (1993). Thus, the NOEL for hexachloroethane is estimated at 261 mg/kg/d[11]. Using the same equation, the LOEL

[9] Subchronic studies are routinely relied upon to extrapolate to chronic toxicity by regulatory agencies, including EPA

[10] NOEC refers to an exposure concentration at which no toxic effect is observed, whereas LOEC refers to the lowest concentration at which a toxic effect is observed.

[11] Calculation: $(0.4089 \times 0.25^{0.77} \times 464 \text{ mg/m}^3) \div 0.25 \text{ kg} = 261 \text{ mg/kg}$

is estimated at 1,416 mg/kg/d, which is 5.4-fold higher than the NOEL[12]. Lastly, the LD_{50} is estimated at >1,416 mg/kg, and, according to EPA's toxicity categorization chart for terrestrial organisms, this would classify hexachloroethane as 'slightly toxic' or 'practically nontoxic' (EPA, 2008). This study further indicates that, similar to 1,1,1-trichloroethane, hexachloroethane is of low toxicity potential to birds; thus providing further support that 1,1,2-trichloroethane is anticipated to have a low toxicity potential in birds when administered under realistic conditions.

Equation 1. $$\boldsymbol{Inhalation\ rate}\left(\frac{m^3}{day}\right) = \mathbf{0.4089} \times \boldsymbol{body\ weight}^{\mathbf{0.77}}(\boldsymbol{kg})$$

3.1.3. Avian Toxicity Data for 1,1,2-Trichloroethane

In identifying chronic avian toxicity as a data need for 1,1,2-trichloroethane, EPA indicated that the available acute toxicity study (i.e., Elovaara et al., 1979) for 1,1,2-trichloroethane reported potential avian toxicity, **though acknowledged the route of exposure was not relevant to likely ecological exposure scenarios**. In the absence of identified chronic toxicity studies for analogues, EPA concluded that it was necessary to conduct further testing to fill this data need.

We agree with EPA's assessment that the route of exposure utilized by Elovaara et al. (1979) is not environmentally relevant. Moreover, the doses used by Elovaara et al. (1979) are high, especially given that the chemical was administered via injection. The authors suggested that the LD_{50} for 1,1,2-trichloroethane lies between 50 and 100 µmol/egg. Using **Equation 2**, the doses of 50 and 100 µmol/egg would respectively translate into approximately 695 and 1,390 mg/kg based on the egg weight reported by Elovaara et al. (1979) and 1,1,2-trichloroethane's molar mass of 133.4 g/mol (**Table 1**). According to the EPA toxicity categorization chart for terrestrial organisms, an LC_{50} of 695 to 1,390 mg/kg would be considered only 'slightly toxic' (EPA, 2008).

Equation 2. $$\boldsymbol{Dose}\left(\frac{\boldsymbol{mg}}{\boldsymbol{kg}}\right) = \boldsymbol{Dose}\left(\frac{\boldsymbol{mol}}{\boldsymbol{egg}}\right) \times \boldsymbol{Molar\ mass}\left(\frac{\boldsymbol{mg}}{\boldsymbol{mol}}\right) \div \boldsymbol{Egg\ weight}\ (\boldsymbol{kg})$$

Further, it should be noted that 1,1,2-trichloroethane is highly volatile, as indicated by its vapor pressure of 23.0 mmHg (**Table 1**); thus, the fate and transport of 1,1,2-trichloroethane following its injection into the air space of the eggs are unclear. Possibly, volatility of 1,1,2-trichloroethane contributes to the reported effects. This hypothesis is supported by comparing the number of malformed embryos among the substances tested by Elovaara et al. (1979). The number of malformed embryos was higher for 1,1,1-trichloroethane than for 1,1,2-trichloroethane; 1,1,1-trichloroethane is more volatile than 1,1,2-trichloroethane, such that its vapor pressure is 124 mmHg (CompTox Chemicals Dashboard, 2020). Consequently, the study by Elovaara et al. (1979) does not permit the exclusion of any artifactual effects that may be due to the chemical's physical properties (i.e., volatility). Additionally, Elovaara et al. (1979) did not perform a statistical analysis, which makes it difficult to deduce whether the reported effects were likely to be related to exposure vs. occurring by random chance.

In addition to testing 1,1,2-trichloroethane, Elovaara et al. (1979) examined the toxicity of several other chlorinated hydrocarbons, including one of the analogues identified by EPA (1,1,1-trichloroethane). Similar effects were reported for 1,1,1-trichloroethane as for 1,1,2-trichloroethane in this study, except that 1,1,1-trichloroethane appeared to have greater effects on egg development than 1,1,2-trichloroethane. Contrary to the results from Elovaara et al. (1979), 1,1,1-trichloroethane acute toxicity via environmentally relevant exposure pathways (oral ingestion or inhalation) would be considered "practically non-toxic" according to the EPA toxicity categorization chart for terrestrial organisms (EPA, 2008). This contradiction

[12] For context, substances that do not elicit effects at 100 mg/kg/d or lower in rodents are not required to be classified as hazards under the Globally Harmonized System of Classification and Labeling (UN, 2019); similar classification schemes are not available for data from bird studies.

is an indication that the experimental construct used by Elovaara, et al. (1979) may not produce results consistent with what would occur under environmentally relevant exposure scenarios.

3.2. The environmental monitoring data EPA cited on 1,1,2-trichloroethane demonstrates that avian species would be exposed to only low levels of the substance, if at all.

To issue a test order for a chemical, EPA must demonstrate that testing is necessary for a risk evaluation. For a chemical to pose a risk to avian species, the chemical must present a hazard (e.g., an adverse effect associated with exposure), and the species must have sufficient exposure from environmental media (e.g., exposure at high enough concentrations to elicit said adverse effect).

In establishing that there is evidence of potential exposure to 1,1,2-trichloroethane by avian species through environmental media, EPA relied on monitoring data from the U.S. Geological Survey (USGS). Details on this monitoring data were not provided in the test order, nor were they presented in the certified index. There is no current evidence that EPA conducted any analysis of this monitoring data to understand overall likelihood of exposure to 1,1,2-trichloroethane. EPA relied on the data in the Water Quality Portal (WQP), a cooperative service sponsored by the USGS, EPA, and the National Water Quality Monitoring Council (NWQMC) (WQP, 2022). The WQP compiles environmental sampling data from over 400 federal, state, tribal, and local agencies, and thus represents a robust resource for understanding the potential for exposure to 1,1,2-trichloroethane. An independent review of available exposure data in the WQP and ATSDR identified additional data on the presence of 1,1,2-trichloroethane in environmental media, including air, soil, sediment, water, and biota, such that a refined understanding of exposures is possible. **Table 4** summarizes environmental media sampling results of 1,1,2-trichloroethane from the WQP. In general, 1,1,2-trichloroethane is infrequently detected across all environmental media reported in the WQP. As exposure is a critical component for a chemical to represent a risk, the absence of 1,1,2-trichloroethane in most environmental samples suggests additional hazard testing for 1,1,2-trichloroethane is not a critical data need.

3.2.1. Air

Recently, ATSDR reviewed available exposure data for 1,1,2-trichloroethane. The agency reported that, where detected, 1,1,2-trichloroethane was typically present in ambient air at concentrations ranging from 10 to 50 ppt (ATSDR, 2021)[13]; for context, 1 ppt is roughly equivalent to a single drop of water in an Olympic-sized swimming pool or 1 second out of roughly 32,000 years. The WQP contains 36 air samples of 1,1,2-trichloroethane that were collected at a railyard and two Superfund sites between 2000 and 2019 (WQP, 2022). 1,1,2-trichloroethane was not detected above the limit of detection in any of the 36 samples in the WQP database. Together with the results presented by ATSDR, this finding indicates that 1,1,2-trichloroethane is infrequently detected in ambient air and, if present, is present at very low concentrations.

3.2.2. Soil

Available data on 1,1,2-trichloroethane in soil samples are largely limited to sites undergoing remediation, which are prone to have higher levels of chemical contamination than typical environments. Even in these studies, detection frequency for 1,1,2-trichloroethane is low. The WQP contains 1,388 measurements of 1,1,2-trichloroethane in soil samples collected between 1993 and 2015 (WQP, 2022). One of these samples was coded as having an invalid result and was excluded from further analysis. Of the remaining 1,387 soil samples, only seven, which were from two Superfund sites, the Ogden Railyard, and an industrial chemical

[13] For comparison, the concentration in air of hexachloroethane, an analogue of 1,1,2-trichloroethane, that was necessary to achieve observed effects in a repeated dose bird study (2,517 mg/m^3 or 260 ppm) was approximately 5,000,000-fold higher than the maximum concentration of 1,1,2-trichloroethane in air reported by ATSDR (50 ppt).

site, had detectable levels of 1,1,2-trichloroethane; concentrations ranged from 4 to 1,410 µg/kg (median = 13 µg/kg). Across the entire WQP database, the detection frequency of 1,1,2-trichloroethane in soil is 0.5%.

3.2.3. Sediment

Similar to soil and air, 1,1,2-trichloroethane is infrequently detected in sediment. The WQP contains 3,778 measurements of 1,1,2-trichloroethane in sediment samples collected between 1982 and 2021 (WQP, 2022). Forty-two of these sample records were coded as having invalid results. Of the remaining 3,736 records, only 44 had detectable levels of 1,1,2-trichloroethane, with concentrations ranging from 1 to 19 µg/kg (median = 11 µg/kg). The samples with detectable levels of 1,1,2-trichloroethane were collected from the EPA Great Lakes National Program, U.S. Army Corp of Engineers in Nashville, Ogden Railyard, and San Ildefonso Pueblo. It is worth noting that 37 of the 44 detect records indicate that the reported value is a maximum, suggesting that the reported concentrations may be overestimates of typical concentrations of 1,1,2-trichloroethane in sediment. The detection frequency of 1,1,2-trichloroethane in sediment in the WQP is 1.2%.

3.2.4. Water

Avian species' potential exposure to 1,1,2-trichloroethane in water is largely expected to be limited to surface water, which has very low detection frequencies. The WQP classifies surface water into estuary, glacier, lake/reservoir/impoundment, ocean, stream, wetland, and aggregate surface-water-use site-types. The aggregate surface-water-use site-type is used *"when it is not possible or practical to describe the specific sites as diversions, outfalls, or land application sites, or when water-use information is only available for the aggregate"* (WQP, 2022).

For streams, the WQP contains 33,456 sample records of 1,1,2-trichloroethane from 1977 to 2022 (WQP, 2022). Of these records, 417 were coded as invalid, preliminary, or provisional, and 32,764 were coded as non-detects. The remaining 275 samples had concentrations of 1,1,2-trichloroethane ranging from 0.001 to 400 µg/L (median = 0.5 µg/L), resulting in a detection frequency of 0.8%.

The WQP contains 2,156 finalized lake, reservoir, or impoundment sample records of 1,1,2-trichloroethane collected from 1982 to 2022 (WQP, 2022). Twenty-one of these samples from the USGS Louisiana Water Science Center, U.S. Army Corp of Engineers in Nashville, and New Mexico Surface Water Quality Bureau were not coded as non-detects, resulting in a 1% detection frequency. The reported 1,1,2-trichloroethane concentration range in lake, reservoir, or impoundment samples was 0.15 to 32.6 µg/L (median = 11 µg/L).

There are 216 ocean sample records in the WQP from 2003 to 2019, of which only one from the California State Water Resources Control Board had a measurable concentration of 1,1,2-trichloroethane (4 µg/L) (WQP, 2022). The detection frequency of 1,1,2-trichloroethane in ocean samples in the WQP is 0.5%.

Finally, the WQP contains 2,120 estuary sample records from 1981 to 2021, of which nine collected by the Louisiana Department of Environmental Quality were not coded as non-detects, resulting in a detection frequency of 0.4% (WQP, 2022). The 1,1,2-trichloroethane concentration in estuary samples ranged from 0.71 to 1,700 µg/L (median = 1.9 µg/L). 1,1,2-Trichloroethane was not detected in any glacier (n = 0), wetland (n = 10), or aggregate surface-water-use samples (n = 2,211) (WQP, 2022).

For subsurface water, the WQP contains 226 samples collected between 1984 and 2012, none of which had detectable levels of 1,1,2-trichloroethane (WQP, 2022).

Westrick et al. (1984) surveyed 945 U.S. groundwater supply sources and found that none contained 1,1,2-trichloroethane above the quantitation limit of 0.5 ppb (or 0.5 µg/L) (Westrick et al., 1984; identified via ATSDR, 2021). The WQP classifies groundwater into springs, wells, and aggregate groundwater use site-types. The WQP uses an aggregate groundwater use site-type *"when it is not possible or practical to describe the specific sites as springs or as any type of well including 'multiple wells', or when water-use information is only available for the aggregate"* (WQP, 2022). For wells, the WQP contains 97,056 sample

records of 1,1,2-trichloroethane from 1980 to 2022 (WQP, 2022). Of these records, 4,928 were coded as invalid or preliminary, and 77,868 were coded as non-detects. Unfortunately, it is difficult to determine how many of the remaining samples had detectable levels of 1,1,2-trichloroethane, as the detection limit appears to be reported as the measured value in many of the samples[14]. The concentration range of 1,1,2-trichloroethane in well samples that were not coded as non-detects ranged from 0.001 to 350,000 µg/L (median = 0.5 µg/L). Five outlier samples had concentration values more than ten times greater (6,400-350,000 µg/L) than the next closest value (620 µg/L); these outliers were all collected in or prior to 1990. If only samples collected in the past ten years are considered, there are 2,577 samples not coded as non-detects, and the concentration range is 0.014 to 20 µg/L (median = 1 µg/L). For springs, four out of 1,238 finalized samples were not coded as non-detected, but each of these samples had a reported value of 1 µg/L, suggesting that these may also be non-detects (WQP, 2022). 1,1,2-Trichloroethane was not detected in any aggregate groundwater use samples (n = 11) (WQP, 2022).

Avian species are expected to primarily come into contact with surface water. Given that 1,1,2-trichloroethane detection frequencies in estuaries, lakes, streams, oceans, and wetlands are less than 1%, birds are unlikely to have significant exposures when they are drinking or swimming in bodies of water.

3.2.5. Biota

Although the WQP does not contain measurements of 1,1,2-trichloroethane in avian species, it does include data from various fish species, which may represent a potential exposure pathway for birds via diet. Specifically, 364 measurements of 1,1,2-trichloroethane were reported in 41 species of freshwater fish in Indiana from 1983 to 1994, and 66 measurements of 1,1,2-trichloroethane were reported in three species of saltwater fish in Hawaii from 2004 to 2014 (WQP, 2022). Of these 430 total samples, only 13 freshwater fish samples from 1985 had measurable amounts of 1,1,2-trichloroethane, with concentrations ranging from 13 to 71 µg/kg (median = 50 µg/kg). The detection frequency of 1,1,2-trichloroethane in fish in the WQP is therefore 3.0%.

Isnard and Lambert (1988; identified via ATSDR, 2021) estimated 1,1,2-trichloroethane to have a bioconcentration factor (BCF) of 17 based on its aqueous solubility and octanol-water partition coefficient. However, the experimentally determined BCF of 1,1,2-trichloroethane is between 2.6 and 6.7, suggesting that there is a low potential for bioaccumulation and supporting the low detection frequency in fish observed in the WQP (NITE, 2022; identified via PubChem). It is anticipated that birds ingesting fish in their diets would have a low likelihood of exposure to 1,1,2-trichloroethane.

[14] In cases where the detection limit is reported, the contaminant is understood to be present at or below that value in the sample.

Table 4. Environmental media sampling results for 1,1,2-trichloroethane identified in the Water Quality Portal from 1977 to 2022.

Environmental media type	Number of samples[‡]	Number of potential detects	Detection frequency
Air	36	0	0%
Soil	1,387	7	0.5%
Sediment	3,736	44	1.2%
Surface water	39,752	306	0.8%
Streams	33,039	275	0.8%
Lakes/reservoirs/impoundments	2,156	21	1.0%
Estuaries	2,120	9	0.4%
Ocean	216	1	0.5%
Wetland	10	0	0%
Aggregate surface-water-use[†]	2,211	0	0%
Glacier	0	0	N/A
Subsurface water	226	0	0%
Groundwater	93,377	14,264	15%
Wells	92,128	14,260[§]	15%
Springs	1,238	4	0.3%
Aggregate groundwater use[‡]	11	0	0%
Biota	430	13	3.0%
Freshwater fish	364	13	3.6%
Saltwater fish	66	0	0%

[†] An aggregate groundwater use site-type is used *"when it is not possible or practical to describe the specific sites as springs or as any type of well including 'multiple wells', or when water-use information is only available for the aggregate"* (WQP, 2022).

[‡] An aggregate surface-water-use site-type is *used "when it is not possible or practical to describe the specific sites as diversions, outfalls, or land application sites, or when water-use information is only available for the aggregate"* (WQP, 2022).

[‡] The number of samples excludes records that were coded as "Preliminary," "Provisional," "Detected Not Quantified," or "Not Reported."

[§] The number of well samples with detects is likely an overestimate, as the detection limit appears to be reported as the measured value in many of the samples. Further, well water is not a relevant exposure pathway for avian species.

Collectively, these data indicate that 1,1,2-trichloroethane is rarely detected in relevant environmental samples, and, if it is, the environmental concentrations would be well below the doses used in the acute and subchronic studies for 1,1,2-trichloroethane analogues (see **Section 3.3.1** for an exemplar comparison). Furthermore, the infrequent detection of 1,1,2-trichloroethane in environmental samples indicates that chronic exposure scenarios for birds are unlikely (i.e., birds are unlikely to have a continuous exposure to 1,1,2-trichloroethane because it is not regularly found in environmental media). This further suggests that chronic toxicity testing data are not a data need. Together, these data indicate that 1,1,2-trichloroethane exposure to birds is unlikely and thus potential for risk to these species is low. EPA should have considered these additional sources of data and analysis on 1,1,2-trichloroethane environmental exposure when evaluating the need for conducting avian reproduction testing, as the presence in relevant environmental media (e.g., "*ground water, sediment, soil, surface water and biota"*) is a key criterion for determining the necessity of additional testing.

3.3. Under TSCA, EPA is required to both consider a tiered testing approach and reduce vertebrate animal testing by considering alternate methodologies. For avian toxicity testing, lower tier assays and new approach methodologies (NAMs) are available for consideration, including computational tools endorsed by the EPA, that could inform on 1,1,2-trichloroethane toxicity as a preliminary step and potentially avoid chronic vertebrate testing. EPA neglected to consider these options for 1,1,2-trichloroethane.

Tiered testing strategies are commonly implemented by regulatory agencies, including EPA, to leverage key information gained from less complex toxicity tests, such as *in vitro*, *in silico*, or screening level assays, to inform the need for and/or study design of more complex assays (Plunkett, et al. 2010). In some instances, results of lower tier testing indicating a low likelihood of toxicity permit avoidance of higher tier testing that is often more costly, cumbersome, and involves a larger number of animals. In determining the need for specific testing under TSCA Section 4, EPA is required to consider tiered testing strategies as well as strategies that will minimize vertebrate animal testing.

According to EPA's document titled Overview on Activities Involved in Issuing a TSCA Section 4 Order , the 2016 amendments to Section 4 of TSCA authorize EPA to issue test orders; however, prior to issuing a test order, the law requires EPA to make *"certain findings and determine the appropriate testing to require"* (EPA, 2022b). The Order must be developed in a manner that identifies the information required, the analyses that were conducted that indicate a need for the information, the testing that will provide the information, and the methodologies or other documents, such as OECD and/or Office of Chemical Safety and Pollution Prevention (OCSPP) test guidelines that can inform the generation of such information (EPA, 2022b). EPA uses standard, globally-recognized test guidelines and NAMs to inform data needs and may also develop new protocols that will enable the development of the needed data. Multiple technical considerations go into determining testing requirements. Ultimately, EPA *"seeks to ensure that the testing generates useful, high-quality data"* (EPA, 2022b). Importantly, EPA must meet *"certain statutory criteria"* as it requires the development of information in the test order, including the following (note: keywords appear in bold):

- Tiered screening and testing process – *"TSCA section 4(a)(4) states that EPA, 'shall employ **a tiered screening and testing process**, under which the results of **screening-level tests or assessments** of available information inform the decision as to whether 1 or more additional tests are necessary.' When EPA requires the development of information under section 4, **EPA must design a tiered-testing strategy** (e.g., determine which screening-level tests would inform additional testing), unless EPA identifies information that suggests advanced testing should be required"* (EPA, 2022b).
- Reduction of testing on vertebrates – *"TSCA section 4(h), which is entitled 'Reduction of testing on vertebrates', requires that EPA **reduce or replace the use of vertebrate animals to the extent practicable and scientifically justified**. EPA must not only consider **reasonably available existing information** prior to requiring vertebrate testing, but must also **encourage the use of scientifically valid test methods that reduce or replace the use of vertebrate animals** (provided that those methods will provide information of equivalent or better scientific quality and relevance). If EPA requires vertebrate testing in an Order issued under 4(a)(2), the Agency must explain why such testing is needed. EPA is also encouraged under section 4(h)(2) to group chemicals into 'scientifically appropriate categories' to reduce testing on the substances within the category"* (EPA, 2022b).

In defaulting to requiring a multi-generation avian reproduction assay to evaluate potential chronic and/or developmental toxicity associated with 1,1,2-trichloroethane, EPA gave little explanation or consideration

of the potential use of a tiered testing approach. Under EPA's biochemical and microbial pesticide program, EPA does not require reproductive toxicity testing or chronic toxicity testing unless earlier tiers of testing indicate it is warranted; such previous tiers include acute toxicity testing (Plunkett, et al. 2010). Empirical data on analogues for 1,1,2-trichloroethane indicate that acute toxicity for 1,1,2-trichloroethane is likely to be low, which suggests there may not be a need for further testing, especially when combined with knowledge about potential exposures (see **Section 3.2**). Further, EPA relies only on acute toxicity testing results from Elovaara et al. (1979) as an indication of potential chronic toxicity; as demonstrated in **Section 3.1.3**, this study suffers from several weaknesses that draw its conclusions into question. Therefore, EPA could have considered a test order requesting acute toxicity testing, which would reduce the burden on animal use, to inform the need for more complex chronic studies, which would require a large number of animals for use.[15]

In addition to acute toxicity testing, alternate methods may also be considered as part of a tiered testing strategy, including *in silico* methods. As part of its tiered-testing approach, EPA published its Strategic Plan to Promote the Development and Implementation of Alternative Test Methods within the TSCA Program in 2018 (EPA, 2022c). The Strategic Plan is composed of (i) identifying, developing, and integrating NAMs for TSCA decisions, (ii) verifying that the NAMs are scientifically reliable and relevant for TSCA decisions, and (iii) implementing the reliable and relevant NAMs for TSCA decisions (EPA, 2022c). In June 2020, EPA released the original NAMs Work Plan that laid out the objectives and strategies, and, in December 2021, EPA released the updated Work Plan (EPA, 2021b). Specifically, the TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, directs EPA to *"**reduce and replace**, to the extent practicable and scientifically justified, the use of vertebrate animals in the testing of chemical substances or mixtures; and promote the development and timely incorporation of alternative test methods or strategies that do not require new vertebrate animal testing"* (EPA, 2022b).

Consequently, computational approaches should be considered by EPA as an alternative source of toxicity information and as part of a tiered testing strategy. The EPA stated that *"[r]easonably available data, computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing"* (EPA, 2022a). From an independent review, we identified several resources for computational methods that would permit an understanding of potential avian toxicity. Specifically, EPA's Web-based Interspecies Correlation Estimation (Web-ICE) application can be used to extrapolate avian LD_{50}s based on mammalian LD_{50}s, allowing for an understanding of potential avian toxicity. Secondly, computational methods have been described and should be considered to investigate toxicity of 1,1,2-trichloroethane in avian species. These available methods are reviewed below.

3.3.1. Web-ICE

In June 2016, the EPA released v3.3 of Web-ICE (EPA, 2017). The Web-ICE application was developed by the EPA and collaborators to enable extrapolation of acute toxicity data to taxa with little or no acute toxicity data for a chemical of interest (EPA, 2016). Specifically, Web-ICE permits interspecies extrapolations for acute toxicity from the known toxicity of the chemical to a species with test data (termed 'surrogate' species) to yield predicted LC_{50}/LD_{50} values in species with no acute toxicity data (EPA, 2016). Acute toxicity, as previously discussed, can be used to inform potential chronic toxicity and is often used

[15] According to OECD test guidelines, acute toxicity testing in birds (OECD 223) requires as few as 5 birds (if using a limit test) and as many as 34 birds (for a full acute toxicity study); reproductive toxicity testing in birds (OECD 206) requires 96-144 birds (at the minimum number of four test groups [e.g., three test substance groups plus one control]; more birds are required if additional test groups are needed), plus offspring resulting from mating.

as a step in a tiered testing strategy to determine whether chronic testing is warranted; as an example, EPA relies on acute toxicity testing results for 1,1,2-trichloroethane (Elovaara, et al., 1979) to rationalize the need for chronic toxicity testing of 1,1,2-trichloroethane.

The Web-ICE models depict the relationship between surrogate and predicted taxon based on a database of acute toxicity values: median effect or lethal water concentrations for aquatic species (EC_{50}/LC_{50}) and median lethal oral doses for wildlife species (LD_{50}) (EPA, 2016). In addition to direct toxicity estimation, Web-ICE can generate Species Sensitivity Distributions (SSDs), which are cumulative distribution functions of toxicity values for multiple species and are used to estimate the hazardous concentration (HC) or hazardous dose (HD)[16] that would be protective of most test species (e.g., 95%) (EPA, 2016).

Several peer-reviewed articles have been published to demonstrate the applicability of the Web-ICE in ecological risk assessment evaluations prior to EPA adoption of the program (e.g., Awkerman et al., 2008, 2009; Dyer et al., 2006, 2008). Importantly, it was stated that *"Web-ICE was developed to support both chemical hazard assessment and ecological risk assessment (ERA) by providing a method to estimate acute toxicity to specific taxa, such as listed species, or to a larger number of taxa (species, genera, families) with known uncertainty. Potential applications of acute toxicity values generated by Web-ICE include the problem formulation phase of an ERA to screen for contaminants of potential concern and in the analysis phase to characterize effects to a larger number of species. The estimation of species-specific toxicity values using WebICE is recommended as an alternative to safety factors typically applied when extrapolating toxicity or risks to taxa without chemical and species-specific toxicity data"* (EPA, 2016). Additionally, it was noted that *"[a]nother potential application of the chemical and taxon-specific acute toxicity estimates generated from ICE models includes input into existing exposure and risk models (e.g., TREX; EPA 2005). Web-ICE generated toxicity values may also be used in the analysis of uncertainty and variability in toxicity to ecological receptors in both screening level and baseline or Tier II ERAs"* (EPA, 2016). Given the utility of Web-ICE, it is unclear why EPA did not attempt to integrate this tool in its evaluation of 1,1,2-trichloroethane to estimate potential toxicity in birds and inform the necessity for chronic and reproductive toxicity testing.

Web-ICE was used herein to evaluate the potential acute toxicity of 1,1,2-trichloroethane and its analogues, as noted in **Table 2**. Briefly, EPA's CompTox Chemicals Dashboard was mined to obtain the available oral LD_{50}s in mammals for all available analogues of 1,1,2-trichloroethane (those identified by EPA as well as those identified independently herein) (**Table 5**). Subsequently, the obtained data were used to:

- Evaluate the similarity of 1,1,2-trichloroethane to its analogues using rat LD_{50}s, which were available for 1,1,2-trichloroethane and six analogues.
- Estimate LD_{50}s in avian species based on data for surrogate species.
- Derive the HD_5 that would be protective of 95% of avian and mammalian species.
- Compare the estimated LD_{50}s and HD_5s[17] for 1,1,2-trichloroethane and its analogues to those of 1,1-dichloroethane and 1,2-dichloroethane, which were exempted from avian toxicity testing.
- Discuss estimated acute toxicity values in the context of chronic exposures.

[16] The HC/HD refers to the exposure concentration/dose that is at a corresponding percentile of the SSD.
[17] The HD_5 specifically refers to the exposure dose that is at the 5th percentile of the SSD.

Table 5. Oral LD_{50}s reported for 1,1,2-trichloroethane and its six analogues, as well as 1,1-dichloroethane and 1,2-dichloroethane.

Chemical	LD_{50} (mg/kg)		
	Rat	Mouse	Other
1,1,2-Trichloroethane	789†, 836, 837	378, 491	-
1,1,1-Trichloroethane	>2,000, 9,600, 11,000	11,240	Guinea pig: 94,700 Rabbit: 5,660 Dog: 750
Hexachloroethane*	4,460	-	-
1,1,1,2,2-Pentachloroethane*	920	-	-
1,1,1,2-Tetrachloroethane	670	-	-
1,1,2,2-Tetrachloroethane	200, 250, 350, 570, 800	-	-
1,2,3-Trichloropropane	120, 140‡, 152, 170, 188, 205	-	Rabbit: 390, 523, 765, 850, 880, 900

* Not included as identified analogues by U.S. EPA in Test Order
† Reported as 0.58 mL/kg; converted to mg/kg using a density of 1.36 g/mL obtained from CompTox Chemicals Dashboard.
‡ Reported as 0.108 mL/kg; converted to mg/kg using a density of 1.30 g/mL obtained from CompTox Chemicals Dashboard.

Evaluation of rat LD_{50}s showed that 1,1,2-trichloroethane resembled 1,1,1,2,2-pentachloroethane, 1,1,1,2-tetrachloroethane, and 1,1,2,2-tetrachloroethane (upper bound) (**Figure 2**). Among the chemicals evaluated, the most toxic chemical in rats was 1,2,3-trichloropropane, whose LD_{50}s were 4-7-fold lower than those of 1,1,2-trichloroethane.

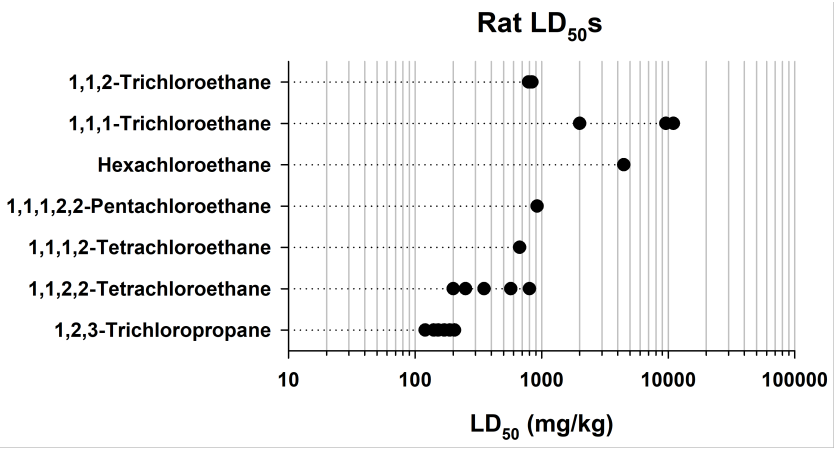


Figure 2. Rat LD_{50}s for 1,1,2-trichloroethane and six analogues (based on data in Table 4).

The estimated avian LD_{50}s obtained from Web-ICE are summarized in **Figure 3** and **Table 6** (for additional details see **Appendix B**). The estimated LD_{50}s for 1,1,2-trichloroethane ranged from 10.22 to 291.52 mg/kg across all species, whereas the LD_{50}s for two commonly used avian species, bobwhite quail (also known as northern bobwhite) and mallard duck, were respectively 58.89 and 222.42 mg/kg. As for the analogues, the estimated LD_{50}s ranged from 5.4 to 4,079.51 mg/kg across all species, depending on the analogue, whereas the estimated LD_{50}s for bobwhite quail and mallard duck ranged respectively from 31.76 to 133.71 mg/kg and from 66.15 to 2,352.61 mg/kg. Among the analogues evaluated, the estimated LD_{50}s for 1,1,2-trichloroethane were the closest to those for 1,1,1,2-tetrachloroethane. The most toxic chemical was 1,2,3-trichloropropane, whose estimated avian LD_{50}s were 2-3-fold lower than those of 1,1,2-trichloroethane. It

is noteworthy that the reported LD_{50} of >2,510 mg/kg and extrapolated LD_{50} of >~523 mg/kg noted for bobwhite quail exposed to 1,1,1-trichloroethane in **Table 2** were approximately 19- and 4-fold greater than the estimated LD_{50} of 133.71 mg/kg noted in **Table 6**, indicating that the estimated values from Web-ICE likely have a degree of conservativism.

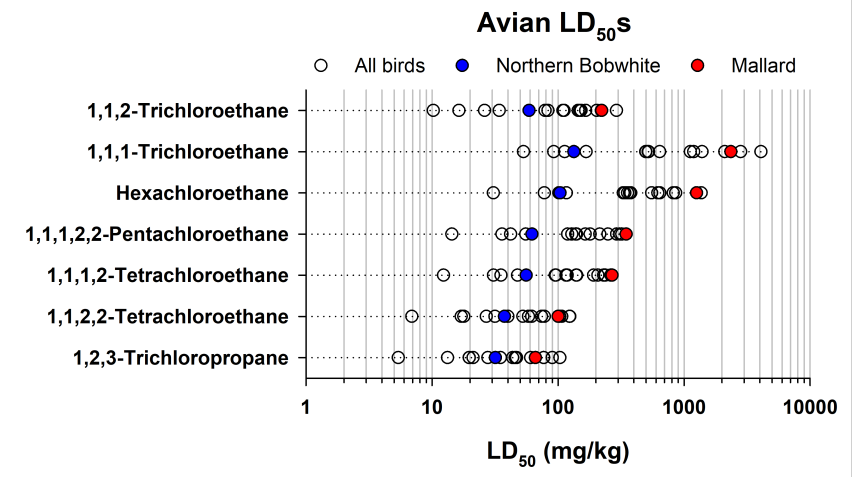


Figure 3. Estimated avian LD_{50}s for 1,1,2-trichloroethane and six analogues (based on data in Appendix B).

Table 6. Estimated LD_{50}s and HD_5s (HD_5s apply to mammalian and avian species).

Chemical	LD_{50}s (mg/kg)			HD_5 (mg/kg)
	All birds	Bobwhite quail	Mallard duck	
1,1,2-Trichloroethane	10.22-291.52	58.89	222.42	21.79
1,1,1-Trichloroethane	53.17-4,079.51	133.71	2,352.61	63.52
Hexachloroethane*	30.66-1368.9	103.98	1,259.52	61.63
1,1,1,2,2-Pentachloroethane*	14.77-347.92	61.96	347.92	32
1,1,1,2-Tetrachloroethane*	12.34-268.68	55.84	268.68	27.81
1,1,2,2-Tetrachloroethane*	6.91-124.38	37.56	100.3	15.65
1,2,3-Trichloropropane	5.4-103.59	31.76	66.15	11.2

* Not identified as analogues by EPA in Test Order
Note: For additional details, see Tables 6-12.

As for hazardous doses that would be protective of 95% of mammalian and avian species, the HD_5 for 1,1,2-trichloroethane was 21.79 mg/kg, whereas the analogue HD_5s ranged from 11.2 to 63.52 mg/kg (**Table 6**). Among the analogues evaluated, the HD_5 for 1,1,2-trichloroethane was the closest to those of 1,1,1,2-tetrachloroethane and 1,1,2,2-tetrachloroethane.

Moreover, the LD_{50} and HD_5 for 1,1,2-trichloroethane are several orders of magnitude higher than would result from the environmental concentrations discussed in **Section 3.2;** in other words, it is improbable that birds would be exposed to levels in the environment that are sufficiently high to cause adverse effects. This point can be illustrated using the following assumptions: (i) 1,1,2-trichloroethane water concentration of 400 µg/L (or 0.4 mg/L) (equivalent to the maximum concentration reported in streams as noted in **Section 3.2**) and (ii) bobwhite quail body weight of 190 g (or 0.19 kg) (EPA, 1993) (bobwhite quail was selected specifically for this example, since it is one of the commonly used avian test species, and its estimated LD_{50} is lower than that of another commonly used test species, mallard duck). **Thus, to achieve the 1,1,2-**

trichloroethane HD_5 of 21.79 mg/kg, the bobwhite quail would have to consume 10.4 L[18] of water in a single day, which is several orders of magnitude higher than the daily water ingestion rate of bobwhite quail (see next paragraph). If the same calculation is repeated with the maximum 1,1,2-trichloroethane water concentration of 32.6 µg/L (or 0.0326 mg/L) reported in lakes as noted in **Section 3.2**, then an even larger volume of water would have to be ingested by the bobwhite quail to achieve the HD_5 (i.e., 127.0 L).

While the LD_{50}s and HD_5s obtained from Web-ICE are applicable to acute toxicity, inferences on chronic toxicity can be made by calculating the amount of water containing 1,1,2-trichloroethane that would be ingested over a lifetime of the bird and comparing it to the amount of water containing 1,1,2-trichloroethane that the bird would need to ingest to achieve the HD_5. For example, the daily water ingestion rate in bobwhite quail is 0.10-0.13 g/g (EPA, 1993). Assuming a body weight of 190 g (as in the paragraph above), a bobwhite quail would ingest 19-25 g (or 19-25 mL, using a water density of 1 g/mL) of water per day. Further, the longevity of a bobwhite quail is 8.5-10.6 months (EPA, 1993). Thus, over a lifetime, a bobwhite quail would ingest approximately 4,845-7,950 mL (or 4.8-8.0 L) of water. Therefore, even if a bobwhite quail did not metabolize and/or excrete ingested 1,1,2-trichloroethane, the amount of 1,1,2-trichloroethane accumulated over its lifetime would still be below the HD_5, . In other words, if a bird consumed water contaminated with 1,1,2-trichloroethane at the maximum concentration detected in the environment every day for its entire lifetime without excreting or metabolizing any of the substance consumed, it still would not reach the dose of 1,1,2-trichloroethane predicted to cause toxicity (e.g. the HD_5).

3.3.2. Computational Methods

Quantitative structure-activity (toxicity) relationships (QSA(T)R) models have been addressed in numerous articles (e.g., Banjare et al., 2015; Basant et al., 2015; Ghosh et al., 2020; Mazzatorta et al., 2006; Mukherjee et al., 2022; Toropov and Benfenati, 2006; Zhang et al., 2015). While the models described in such articles are complex, they demonstrate that avian toxicity can be predicted using computational tools, in lieu of defaulting to requiring vertebrate testing. These computational models offer EPA another available resource, not previously considered, to predict avian toxicity of 1,1,2-trichloroethane.

Key aspects of select studies are summarized in **Table 7**. Collectively, the studies indicate that several computational methods have been or can be developed to enable high-throughput screening-level toxicity assessments of chemicals in birds. Specifically, the developed models were successfully employed to assess toxicity of a myriad of pesticides and industrial chemicals in multiple bird species (e.g., Zhang et al. (2015) evaluated >663 chemicals in 17 avian species), and several models even permitted the deduction of key chemical features that render chemicals more toxic (e.g., Banjare et al. (2015) showed that avian toxicity is influenced by the presence of phosphate and halogens, whereas Mukherjee et al. (2022) noted that the presence of electronegative and lipophilic features greatly enhanced pesticide toxicity). Importantly, the models were validated to ensure accuracy and were reported to have a good predictive power (e.g., Basant et al. (2015) reported R^2 values[19] of >0.9 when comparing measured and predicted toxicity values). Thus, these (or similar) computational methods, as appropriate, can and should be incorporated into the tiered testing strategy given their potential to enable high-throughput screening level assessments for multiple chemicals and in multiple avian species.

[18] Calculation: 21.79 mg/kg×0.19 kg÷0.4 mg/L=10.4 L
[19] R^2 values range from 0 to 1; the closer the R^2 to 1, the more accurate the correlation.

Table 7. Examples of studies that utilized QSA(T)R methods to evaluate chemical toxicity in birds.

Study	Description	Findings
Mazzatorta et al. (2006)	• Investigated relationship between structural properties of 116 pesticides and avian oral toxicity • Collected physicochemical and structural descriptors for the pesticides • Evaluated the resulting dataset using principal component analysis and various algorithms • Obtained a final model using a support vector machine (SVM) combined with genetic algorithms for feature selection	• The model had a good predictive ability • Descriptor analysis indicated the prominent role of the interaction of pesticides with macromolecules and/or proteins in the mechanism of action
Banjare et al. (2015)	• Developed classification-based quantitative structure toxicity relationship (QSTR) models for 516 diverse pesticides in mallard duck, bobwhite quail, and zebra finch following OECD guidelines • Reliability and robustness of models were ensured using different statistical metrics • Relied on external compounds to highlight the predictive nature of the models • Verified model reliability by the application of the standardization approach of the applicability domain (AD)	• Revealed that avian toxicity is influenced by the presence of phosphate, halogens (Cl, Br), ether linkage, and NCOO • The models provided *a priori* toxic and non-toxic classification for unknown pesticides (inside AD), with particular emphasis on organophosphate pesticides • Interspecies toxicity correlation and predictions encouraged for the fulfilment of data gaps in vital missing species
Basant et al. (2015)	• Developed tree-based multispecies QSAR models to predict avian toxicity of pesticides using a set of nine descriptors from the chemical structures and relying on a dataset of 4,768 chemicals • Used bobwhite quail toxicity data to construct three QSAR models (SDT, DTF, DTB) that were externally validated using toxicity data in mallard duck, ring-necked pheasant, Japanese quail, and house sparrow • Tested the external predictive power of the QSAR models through validation deriving a wide series of statistical checks	• The DTF and DTB performed better than SDT (R^2 of 0.945 and 0.966 between the measured and predicted toxicity values) • Both models performed well in four other test species ($R^2 > 0.918$) • Identified substructure alerts responsible for avian toxicity • Models can be used in screening new pesticides for regulatory purposes
Zhang et al. (2015)	• Assessed the toxicity of >663 chemicals in 17 avian species • Classified chemicals into highly toxic, slightly toxic and non-toxic, based on EPA toxicity classification • Used chemical category approaches with molecular descriptors and five commonly used fingerprints to develop five machine learning methods • Evaluated methods in mallard duck and bobwhite quail	• The support vector machine (SVM) method with Pubchem fingerprint performed best as revealed by 5-fold cross-validation and the external validation set on Japanese quail • No species difference existed in database despite several chemicals with different toxicity on some avian species • The best model had an overall accuracy of 0.851 • Identified several representative substructures for characterizing avian toxicity • Study provides a new tool for chemical safety assessment
Ghosh et al. (2020)	• Relied on classification and regression-based QSAR models to model toxicity of 56 industrial chemicals in bird *A. platyrhynchos* • Validated models by employing internal and external validation metrics followed by randomization test, AD study, and intelligent consensus prediction of all individual models	• Revealed that chemical features like topological distance of 1, 3, and 5 between atoms O-P, C-P, and N-S, correspondingly, along with the CR3X fragment, can be responsible for an increase in toxicity, whereas the presence of S-Cl with topological distance 6 is associated with lower toxicity

Study	Description	Findings
		• Developed models offer evidence and guidance in the framework of virtual screening as well as a toxicity prediction of new and/or untested chemical libraries
Mukherjee et al. (2022)	• Developed regression-based two-dimensional quantitative structure toxicity relationship (2D QSTR) and quantitative structure toxicity-toxicity relationship (QSTTR) models to estimate toxicity of pesticides in five avian species following OECD guidelines • Validated models using different statistical internal and external parameters to ensure robustness and interpretability • Developed QSTTR models have been employed to the *in silico* toxicity prediction of 124, 154, and 250 pesticides against bobwhite quail, ring-necked pheasant, and mallard duck, respectively, extracted from the Office of Pesticides Program (OPP) Pesticide Ecotoxicity Database	• The presence of electronegative and lipophilic features greatly enhanced pesticide toxicity, whereas the hydrophilic characters had a detrimental impact on pesticide toxicity • The information obtained from the modeled descriptors might be useful for pesticide risk assessment in the future, with the added benefit of providing an early caution of possible adverse impact on birds for regulatory purposes

3.3.3. Concluding Remarks on Tiered Testing and Computational Tools

Based on the information provided in the test order for 1,1,2-trichloroethane, it is apparent that EPA neglected to consider lower tiered toxicity testing (e.g., acute) or computational tools in its tiered testing strategy for 1,1,2-trichloroethane in advance of requiring chronic vertebrate toxicity testing. Instead, the EPA stated that *"[r]easonably available data, computational toxicology, or high-throughput screening methods and prediction models are not available and/or cannot be used to address the avian reproduction testing"* (EPA, 2022a). Existing acute toxicity studies on 1,1,2-trichloroethane are flawed with respect to study design and interpretation of results in the absence of statistical analyses. Therefore, acute toxicity testing remains a data gap that should be addressed prior to requiring chronic toxicity testing. This could be accomplished via animal testing, read-across from analogues, or as described in detail, computational modeling. As demonstrated herein, EPA's Web-ICE tool can be implemented to extrapolate acute toxicity in avian species using mammalian toxicity data. Subsequently, the estimated avian toxicity values can be discussed in the context of environmental exposures to have a better picture of toxicity potential. Additionally, the estimated acute toxicity values can be used to make inferences on chronic toxicity. Moreover, several computational models have been developed that permit high-throughput screening-level assessments to evaluate the toxicity of pesticides and industrial chemicals in multiple avian species. These models, while complex, can significantly contribute to EPA's efforts, thereby minimizing vertebrate testing. If the EPA had considered these tools in assessing the need for chronic avian testing on 1,1,2-trichloroethane, this could have impacted the decision that an avian reproduction test is necessary for 1,1,2-trichloroethane.

4. CONCLUSIONS

EPA failed to consider key information that is publicly available when determining the need for chronic avian toxicity testing for 1,1,2-trichloroethane. Specifically, EPA failed to identify analogues for which additional toxicity information could be used to inform potential avian toxicity for 1,1,2-trichloroethane. Based on the existing studies, 1,1,2-trichloroethane and its analogues 1,1,1-trichloroethane and hexachloroethane appear to have low toxicity potential in avian species, including, where available, in repeated dose toxicity studies. In lieu of additional testing for 1,1,2-trichloroethane, it is possible to

consider read-across from existing literature on analogues. In addition to analogues, EPA disregarded tiered testing that could inform potential avian toxicity of 1,1,2-trichloroethane. For example, several computational tools are available for predicting avian toxicity, including a tool sponsored by EPA (Web-ICE). Specifically, Web-ICE assessments demonstrate that the estimated LD_{50}s in birds would be several orders of magnitude higher than potential exposures to birds via environmental media, based on measured concentrations. Other computational tools should also be considered, since several peer-reviewed published articles were identified in which QSA(T)R models were implemented to evaluate toxicity in several avian species. Consideration of recommendations expressed herein will help ensure EPA's commitment to its efforts in reducing animal testing (EPA, 2021b). Furthermore, given the poor quality of acute toxicity data on which EPA based their decision for issuing the test order (e.g., Elovaara, et al. (1979)), an alternate option would be to clarify avian toxicity potential via an acute toxicity study before defaulting to a multi-generation reproductive avian toxicity study, which requires larger numbers of animals (in direct conflict with the mandate to reduce vertebrate animal testing). Lastly, careful consideration of the exposure data (for which EPA did not conduct analysis to understand exposure probability) indicates that 1,1,2-trichloroethane is not routinely detected in environmental media above the limits of detection/quantitation. Therefore, the potential for risk in the absence of substantial exposure is likely very low, and the identified data gap should not be considered a data need.

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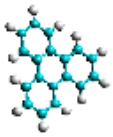
APPENDIX A

Analog Report
For



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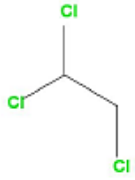
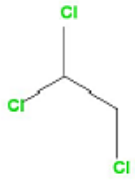


7 AIM Results Found

Exact Chemical Match

1,1,2-TRICHLOROETHANE [79-00-5]
ClCC(Cl)Cl



Toxicity Data Available for this Compound

- RTECS
- HPV Challenge
  - OECD HPV
    ** May also be located at: OECD*
- ECOTOX
- TSCATS II
- ACToR
- TSCATS
- IRIS
- HSDB
- IUCLID
- NTP
- ATSDR
- DSSTox
- HPVIS

Mar 10, 2022 10:49 AM 1

Exact Chemical Match

1,1,2-TRICHLOROETHANE [79-00-5]
ClCC(Cl)Cl

- This compound may metabolize in the body to products that may cause concerns for human health. Analogs for metabolites should also be investigated. Alkyl halide

---

TRICHLOROETHANE [25323-89-1]
ClC(Cl)CCl

Toxicity Data Available for this Compound

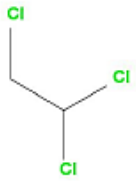
ECOTOX

TSCATS II

ACToR

TSCATS

HSDB



- This compound may metabolize in the body to products that may cause concerns for human health. Analogs for metabolites should also be investigated. Alkyl halide

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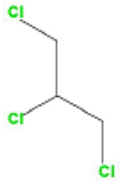
Analogs

1,2,3-TRICHLOROPROPANE [96-18-4]
ClCC(Cl)CCl



Toxicity Data Available for this Compound

RTECS

HPV Challenge

OECD HPV

** May also be located at:* OECD

ECOTOX

TSCATS II

ACToR

TSCATS

IRIS

HSDB

IUCLID

NTP

ATSDR

DSSTox

HPVIS

- This compound may metabolize in the body to products that may cause concerns for human health. Analogs for metabolites should also be investigated. Alkyl halide

---

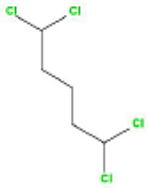
Analogs

1,1,5,5-Tetrachloropentane [17655-64-0]
ClC(Cl)CCCC(Cl)Cl

Toxicity Data Available for this Compound

ACToR

DSSTox



1,1,2,3-TETRACHLOROPROPANE [18495-30-2]
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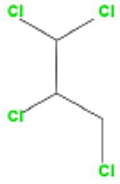
Toxicity Data Available for this Compound

TSCATS II

TSCATS



- This compound may metabolize in the body to products that may cause concerns for human health. Analogs for metabolites should also be investigated. Alkyl halide

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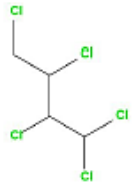
Analogs

BUTANE, PENTACHLORO- [31391-27-2]
C(C(C(C(Cl)Cl)Cl)Cl)Cl

Toxicity Data Available for this Compound

RTECS

ACToR



- This compound may metabolize in the body to products that may cause concerns for human health. Analogs for metabolites should also be investigated. Alkyl halide

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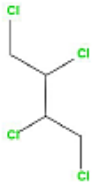
1,2,3,4-TETRACHLOROBUTANE [3405-32-1]
ClCC(Cl)C(Cl)CCl

Toxicity Data Available for this Compound

RTECS

ACToR



- This compound may metabolize in the body to products that may cause concerns for human health. Analogs for metabolites should also be investigated. Alkyl halide

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APPENDIX B

Table 1. Web-ICE assessment for 1,1,2-trichloroethane (surrogate LD_{50}s in mg/kg: rat: 789, mouse: 378; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	111.94	12.41 - 1009.73	Norway rat (Rattus norvegicus)
Chicken	144.61	71.42 - 292.82	Mouse (Mus musculus)
Chukar	152.56	52.73 - 441.40	Norway rat (Rattus norvegicus)
Common grackle	26.12	10.93 - 62.45	Mouse (Mus musculus)
Gray partridge	291.52	123.46 - 688.35	Norway rat (Rattus norvegicus)
House finch	16.35	6.54 - 40.83	Mouse (Mus musculus)
House sparrow	165.93	114.39 - 240.69	Mouse (Mus musculus)
Japanese quail	221.34	164.27 - 298.23	Mouse (Mus musculus)
Mallard	222.42	111.00 - 445.70	Mouse (Mus musculus)
Northern bobwhite	58.91	25.67 - 135.20	Norway rat (Rattus norvegicus)
Red billed quelea	10.22	4.84 - 21.57	Mouse (Mus musculus)
Red-legged partridge	203.3	94.65 - 436.66	Norway rat (Rattus norvegicus)
Redwinged blackbird	82.97	57.09 - 120.58	Mouse (Mus musculus)
Ring-necked pheasant	78.75	41.63 - 148.98	Mouse (Mus musculus)
Rock dove	34.16	17.52 - 66.57	Mouse (Mus musculus)
Sharp-tailed grouse	109.42	27.35 - 437.76	Mouse (Mus musculus)
Starling	148.8	76.28 - 290.27	Mouse (Mus musculus)

Note: These data were generated using Web-ICE SSD function. When multiple surrogates are entered, Web-ICE selects the best fitted prediction.

Table 2. Web-ICE assessment for 1,1,1-trichloroethane (surrogate LD_{50}s in mg/kg: rat: 9600, mouse: 11240, guinea pig: 94700, rabbit: 5660, dog: 750; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	1,123.66	21.07 - 59,919.53	Norway rat (Rattus norvegicus)
Chicken	2,109.13	438.11 - 10,153.66	Mouse (Mus musculus)
Chukar	520.34	97.00 - 2,791.12	Norway rat (Rattus norvegicus)
Common grackle	113.06	26.88 - 475.43	Norway rat (Rattus norvegicus)
Gray partridge	1389.69	307.22 - 6,286.12	Norway rat (Rattus norvegicus)
House finch	92.33	63.45 - 134.36	Rabbit (Oryctolagus cuniculus)
House sparrow	2,814.07	1,279.93 - 6,187.04	Norway rat (Rattus norvegicus)
Japanese quail	4,079.51	1,971.03 - 8,443.50	Mouse (Mus musculus)
Mallard	2352.61	605.45 - 9,141.56	Norway rat (Rattus norvegicus)
Northern bobwhite	133.71	35.04 - 510.15	Norway rat (Rattus norvegicus)
Red billed quelea	53.17	10.53 - 268.43	Mouse (Mus musculus)
Red-legged partridge	497.33	121.45 - 2,036.48	Norway rat (Rattus norvegicus)
Redwinged blackbird	641.63	281.01 - 1,465.02	Norway rat (Rattus norvegicus)
Ring-necked pheasant	524.72	167.62 - 1,642.54	Norway rat (Rattus norvegicus)
Rock dove	167.35	43.78 - 639.62	Norway rat (Rattus norvegicus)
Sharp-tailed grouse	1,195.89	82.05 - 17,429.86	Norway rat (Rattus norvegicus)
Starling	499.37	140.90 - 1,769.87	Norway rat (Rattus norvegicus)

Note: These data were generated using Web-ICE SSD function. When multiple surrogates are entered, Web-ICE selects the best fitted prediction.

Table 3. Web-ICE assessment for hexachloroethane (surrogate LD_{50} in mg/kg: rat: 4460; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	553.77	18.17 - 16868.63	Norway rat (Rattus norvegicus)
Chicken	620.39	151.53 - 2539.83	Norway rat (Rattus norvegicus)
Chukar	357.12	80.91 - 1576.29	Norway rat (Rattus norvegicus)
Common grackle	77.71	21.85 - 276.34	Norway rat (Rattus norvegicus)
Gray partridge	860.66	236.94 - 3126.22	Norway rat (Rattus norvegicus)
House finch	101.77	19.86 - 521.42	Norway rat (Rattus norvegicus)
House sparrow	1368.9	695.92 - 2692.68	Norway rat (Rattus norvegicus)
Japanese quail	822.17	401.75 - 1682.54	Norway rat (Rattus norvegicus)
Mallard	1259.52	383.86 - 4132.70	Norway rat (Rattus norvegicus)
Northern bobwhite	103.98	32.08 - 337.02	Norway rat (Rattus norvegicus)
Red billed quelea	30.66	6.14 - 152.99	Norway rat (Rattus norvegicus)
Red-legged partridge	377.97	114.31 - 1249.77	Norway rat (Rattus norvegicus)
Redwinged blackbird	370.31	182.24 - 752.48	Norway rat (Rattus norvegicus)
Ring-necked pheasant	339.48	124.99 - 922.07	Norway rat (Rattus norvegicus)
Rock dove	116.54	35.90 - 378.29	Norway rat (Rattus norvegicus)
Sharp-tailed grouse	644.18	61.09 - 6792.07	Norway rat (Rattus norvegicus)
Starling	330.09	109.75 - 992.82	Norway rat (Rattus norvegicus)

Note: These data were generated using Web-ICE SSD function.

Table 4. Web-ICE assessment for 1,1,1,2,2-pentachloroethane (surrogate LD_{50} in mg/kg: rat: 920; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	128.99	12.89 - 1,290.12	Norway rat (Rattus norvegicus)
Chicken	249.52	93.80 - 663.70	Norway rat (Rattus norvegicus)
Chukar	164.52	54.85 - 493.38	Norway rat (Rattus norvegicus)
Common grackle	35.91	14.17 - 91.00	Norway rat (Rattus norvegicus)
Gray partridge	320.89	131.60 - 782.43	Norway rat (Rattus norvegicus)
House finch	42.04	12.88 - 137.14	Norway rat (Rattus norvegicus)
House sparrow	310.42	194.37 - 495.78	Norway rat (Rattus norvegicus)
Japanese quail	291.9	177.06 - 481.22	Norway rat (Rattus norvegicus)
Mallard	347.92	148.23 - 816.63	Norway rat (Rattus norvegicus)
Northern bobwhite	61.96	26.23 - 146.31	Norway rat (Rattus norvegicus)
Red billed quelea	14.37	4.58 - 45.02	Norway rat (Rattus norvegicus)
Red-legged partridge	214.8	96.74 - 476.92	Norway rat (Rattus norvegicus)
Redwinged blackbird	119.4	73.19 - 194.78	Norway rat (Rattus norvegicus)
Ring-necked pheasant	138.49	67.20 - 285.39	Norway rat (Rattus norvegicus)
Rock dove	55.32	23.56 - 129.89	Norway rat (Rattus norvegicus)
Sharp-tailed grouse	180.2	32.48 - 999.58	Norway rat (Rattus norvegicus)
Starling	140.74	64.43 - 307.44	Norway rat (Rattus norvegicus)

Note: These data were generated using Web-ICE SSD function.

Table 5. Web-ICE assessment for 1,1,1,2-tetrachloroethane (surrogate LD_{50} in mg/kg: rat: 670; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	96.26	11.89 - 779.16	Norway rat (Rattus norvegicus)
Chicken	207.79	84.54 - 510.72	Norway rat (Rattus norvegicus)
Chukar	140.8	50.53 - 392.26	Norway rat (Rattus norvegicus)
Common grackle	30.75	12.97 - 72.93	Norway rat (Rattus norvegicus)
Gray partridge	263.2	115.11 - 601.80	Norway rat (Rattus norvegicus)
House finch	35.2	11.75 - 105.41	Norway rat (Rattus norvegicus)
House sparrow	230.41	149.51 - 355.09	Norway rat (Rattus norvegicus)
Japanese quail	237.08	149.21 - 376.71	Norway rat (Rattus norvegicus)
Mallard	268.68	121.99 - 591.79	Norway rat (Rattus norvegicus)
Northern bobwhite	55.84	25.06 - 124.38	Norway rat (Rattus norvegicus)
Red billed quelea	12.34	4.31 - 35.33	Norway rat (Rattus norvegicus)
Red-legged partridge	191.74	92.32 - 398.22	Norway rat (Rattus norvegicus)
Redwinged blackbird	95.12	60.57 - 149.37	Norway rat (Rattus norvegicus)
Ring-necked pheasant	115.66	59.06 - 226.49	Norway rat (Rattus norvegicus)
Rock dove	47.63	21.57 - 105.16	Norway rat (Rattus norvegicus)
Sharp-tailed grouse	139.52	28.42 - 684.77	Norway rat (Rattus norvegicus)
Starling	118.59	57.59 - 244.20	Norway rat (Rattus norvegicus)

Note: These data were generated using Web-ICE SSD function.

Table 6. Web-ICE assessment for 1,1,2,2-tetrachloroethane (surrogate LD_{50} in mg/kg: rat: 200; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	31.53	7.94 - 125.25	Norway rat (Rattus norvegicus)
Chicken	103.44	54.01 - 198.07	Norway rat (Rattus norvegicus)
Chukar	77.76	36.09 - 167.56	Norway rat (Rattus norvegicus)
Common grackle	17.02	9.14 - 31.71	Norway rat (Rattus norvegicus)
Gray partridge	123.63	62.76 - 243.53	Norway rat (Rattus norvegicus)
House finch	17.88	8.01 - 39.92	Norway rat (Rattus norvegicus)
House sparrow	73.95	52.84 - 103.49	Norway rat (Rattus norvegicus)
Japanese quail	107.26	74.54 - 154.35	Norway rat (Rattus norvegicus)
Mallard	100.3	56.67 - 177.54	Norway rat (Rattus norvegicus)
Northern bobwhite	37.56	20.41 - 69.10	Norway rat (Rattus norvegicus)
Red billed quelea	6.91	3.32 - 14.34	Norway rat (Rattus norvegicus)
Red-legged partridge	124.38	70.59 - 219.15	Norway rat (Rattus norvegicus)
Redwinged blackbird	39.97	28.29 - 56.49	Norway rat (Rattus norvegicus)
Ring-necked pheasant	58.2	35.13 - 96.43	Norway rat (Rattus norvegicus)
Rock dove	26.92	15.08 - 48.02	Norway rat (Rattus norvegicus)
Sharp-tailed grouse	52.59	16.38 - 168.80	Norway rat (Rattus norvegicus)
Starling	61.73	36.31 - 104.94	Norway rat (Rattus norvegicus)

Note: These data were generated using Web-ICE SSD function.

Table 7. Web-ICE assessment for 1,2,3-trichloropropane (surrogate LD_{50}s in mg/kg: rat: 120, rabbit: 390; see Table 4 in Section 3.3).

Common Name	Estimated Toxicity	95% Confidence Intervals	Surrogate
Canada goose	19.68	6.10 - 63.42	Norway rat (Rattus norvegicus)
Chicken	77.03	42.84 - 138.49	Norway rat (Rattus norvegicus)
Chukar	60.51	30.73 - 119.17	Norway rat (Rattus norvegicus)
Common grackle	13.26	7.81 - 22.51	Norway rat (Rattus norvegicus)
Gray partridge	89.84	45.64 - 176.83	Norway rat (Rattus norvegicus)
House finch	19.72	16.37 - 23.75	Rabbit (Oryctolagus cuniculus)
House sparrow	45.75	33.10 - 63.23	Norway rat (Rattus norvegicus)
Japanese quail	76.72	54.02 - 108.97	Norway rat (Rattus norvegicus)
Mallard	66.15	40.18 - 108.88	Norway rat (Rattus norvegicus)
Northern bobwhite	31.76	18.28 - 55.19	Norway rat (Rattus norvegicus)
Red billed quelea	5.4	2.92 - 10.00	Norway rat (Rattus norvegicus)
Red-legged partridge	103.59	59.12 - 181.50	Norway rat (Rattus norvegicus)
Redwinged blackbird	27.71	19.92 - 38.56	Norway rat (Rattus norvegicus)
Ring-necked pheasant	43.54	27.62 - 68.66	Norway rat (Rattus norvegicus)
Sharp-tailed grouse	34.82	12.55 - 96.63	Norway rat (Rattus norvegicus)
Starling	46.85	29.09 - 75.44	Norway rat (Rattus norvegicus)

Note: These data were generated using Web-ICE SSD function. When multiple surrogates are entered, Web-ICE selects the best fitted prediction.